



(11)

**EP 0 756 877 A2**

(12)

**EUROPEAN PATENT APPLICATION**

(51) Int Cl.<sup>6</sup>: **A61N 1/372**

(21) Application number: 96305681.7

**(22) Date of filing: 01.08.1996**

(84) Designated Contracting States:  
DE ES FR GB IT NL

**(72) Inventor: Snell, Jeffery D.**  
**Oak Park, California 91301 (US)**

(30) Priority: 02.08.1995 US 510365

**(74) Representative: Roberts, Gwilym Vaughan et al  
KILBURN & STRODE,  
30 John Street  
London WC1N 2DD (GB)**

**(71) Applicant: Pacesetter, Inc.**  
**Sylmar, California 91392-9221 (US)**

**(54) Decision support system and method for an implantable cardiac stimulating device**

(57) This invention provides a therapy decision support system (20) and method for guiding physicians and medical technicians in optimizing a set of adjustable parameters that define the operating characteristics of implantable cardiac stimulating devices. The invention also provides an implantable cardiac stimulating device (38) programmer which can furnish therapy decision support as well as telemetric data retrieval and telemetric programming capabilities.

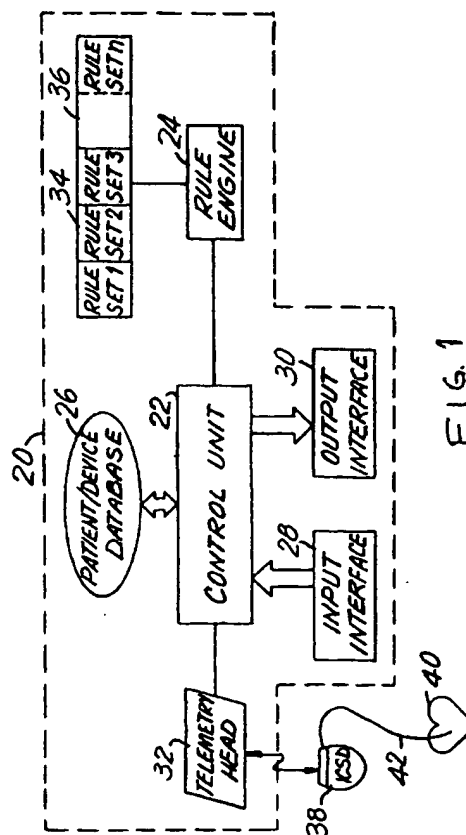


Fig. 1

**EP 0 756 877 A2**

## Description

This invention relates to implantable cardiac stimulating devices, and in particular to a programming system for implantable cardiac stimulating devices. More particularly, this invention provides a therapy decision support system and method that allows physicians and clinical technicians to optimize a set of adjustable parameters that define the operating characteristics of implantable cardiac stimulating devices.

Implantable cardiac stimulating devices are designed to treat cardiac pathologies known collectively as arrhythmias. The term "arrhythmia" refers to the failure of cardiac tissue to contract and relax in a regular, rhythmic fashion. There are two variables that generally define an arrhythmia -- heart rate and heart beat regularity. For example, if a heart beats at a regular but slower than normal rate, the arrhythmia is referred to as "bradycardia". A regular but faster than normal heart rate is referred to as "tachycardia". Finally, chaotic cardiac activity is known as "fibrillation".

The purpose of an implantable cardiac stimulating device is to detect and terminate cardiac arrhythmias in a patient. Typically, this is accomplished by monitoring cardiac activity (e.g., the intracardiac electrogram, or "IEGM") of a patient through various sensors, and by delivering therapeutic electrical stimulation whenever an arrhythmia is detected. As different arrhythmias require different forms of therapy, historically, different classes of implantable devices have been used to treat them. Thus, "pacemakers" generally deliver low energy pulses for treating bradycardia, "cardioverters" deliver stronger pulses for reverting tachycardia, and "defibrillators" deliver very strong pulses or "shocks" for terminating fibrillation. Modern devices may be capable of providing "tiered therapy," in which the type of electrical stimulation supplied by the device is determined according to the severity of the arrhythmia, with more aggressive therapy being applied in response to the more severe arrhythmias. For example, a modern device may serve as a pacemaker and a cardioverter/defibrillator, which is to say, that it can provide therapy for bradycardia, tachycardia and fibrillations.

As medical science and technology progress, treatments for cardiac arrhythmias, and the implantable devices used for their delivery, have become more specific and more sophisticated. Typically, a set of adjustable parameters in the device is programmed to modify the delivered therapy according to the instructions of a physician. These may include parameters that adjust detection mode and detection criteria of the device -- for example, parameters that define bradycardia, tachycardia and fibrillation according to rate and regularity, or parameters that determine whether the device sensors act in one or two chambers of the heart (i.e. single- or dual-chamber sensing).

Other adjustable parameters determine the pacing mode or the specifications of the therapy that the device would deliver in response to any particular arrhythmia that is detected. For example, a device can be programmed to deliver pacing pulses in one or two chambers of the heart (i.e. single- or dual-chamber pacing), with or without modulation of the pacing rate according to the detected heartbeat.

Parameters that relate to routine or house-keeping functions of the device can also be programmed according to the instructions of a physician. For example, the device can be programmed to record the history of a particular episode of arrhythmia, such as the date and time of detection, heart rate at the time of detection, and result of the therapy. Various other sensor and memory storage units within the device can also be enabled or disabled to enhance the performance of the device and battery longevity, as deemed appropriate by the physician.

Obviously, the greater the number of adjustable parameters, the greater the chance of satisfying particular therapeutic needs of each patient by tailoring those parameters. But there is also greater complexity and more room for confusion in deciding what the appropriate settings should be. Incorrect programming of the device, or presence of two or more conflicting parameter settings may lead to device malfunction. It may, for example, cause delivery of unnecessary or inappropriate pulses -- a phenomenon that is categorized as "pacemaker syndrome".

Thus, an immense burden is placed on the physician or the medical technician who must determine the appropriate settings. To make reliable decisions, a physician would need familiarity with vast volumes of information. Not only must physicians keep abreast of the literature and the latest medical advances in the field, they must also understand the complexities of various intricate implantable devices. With new and more sophisticated devices from different manufacturers entering the market at an increasingly rapid pace, this task is becoming more formidable every day.

In spite of some recent attempts in the art to lighten the burden of the therapy decision-making process, known systems generally have not advanced beyond recommending an optimum pacing mode for implantable pacemakers. For example, Bernstein and Parsonnet have described a computer implementation of an algorithm that calculates a pacing mode based on 11 pieces of encoded data entered by the operating physician (presented at the "39th Annual Science Session of the American College of Cardiology," New Orleans, LA - March 1990). Similarly, Garber et al. has programmed an algorithm on a personal computer that can determine an optimum pacing mode following a question-and-answer session with the physician (J. Electrophys. (1989) 3, 217-220).

Simply recommending a pacing mode, however, is unsatisfactory. It can leave the physician unaware of why a particular mode was recommended, what alternatives are available, or how to set the other adjustable parameters on the implantable device. Furthermore, as mentioned previously, in many cases two settings may interfere with each other's function and such a conflict may easily escape the physician's notice. The recommendations made by the prior art systems are also restricted to only one type of implantable cardiac stimulating device whereas a physician must

typically deal with many different devices from various manufacturers.

Therefore, it would be desirable if a decision support system could present the physician with a list of a multitude of available parameters that can be adjusted in an implantable device, and if it could make setting recommendations on any of those parameters according to the physician's choice. Furthermore, it would be desirable if the system could identify possible conflicts among parameter settings and warn the physician accordingly. It would also be desirable if the decision support system presented literature citations or scientific data and reasoning explaining why a particular mode or a specific parameter setting was recommended. To expand the utility of a decision support system it would also be desirable if the decision support system had the flexibility to recognize various types and models of implantable cardiac stimulating devices and make recommendations accordingly.

Another shortcoming of the known computer-based systems is that they require the physician to perform various tasks on a number of different machines or instruments before programming an implantable device. For example, to provide a properly programmed device for a new patient, a physician first has to obtain a large amount of data regarding the patient's medical condition, possibly from a central hospital database, and then enter this data into the computer (e.g., a "personal computer") on which the system is operating. Next, the physician must provide the system with the specifications of the implantable device and the present settings of the adjustable parameters in the device. This information is typically available through apparatus known as a "device programmer," which can communicate with the implantable device telemetrically. Once the system is provided with all the necessary information, it can recommend a pacing mode. The physician must then go back to the device programmer, and adjust the implantable device parameters telemetrically. Having now programmed the device, the physician would have to return to the patient file or database and make a record of the settings for future reference.

Clearly, this mode of operation is cumbersome, inefficient and overly time-consuming. Therefore, a decision support system that could gather some or all of the relevant data automatically would be desirable. It would also be desirable if the same decision support system could arrive at optimal settings for device parameters after gathering the data, and if the same system could automatically program the implantable device according to the instructions of the physician.

### Summary of the Invention

In accordance with the present invention, a decision support system is provided that can generate recommendations for programming of implantable cardiac stimulating devices, according to rules from one or more rule sets that define the operations of various cardiac stimulating devices. Rule sets are selected based on the type of the implantable cardiac stimulating device to be programmed. The system utilizes a rule engine unit that engages an operator in an interactive question and answer session according to the rules of the selected rule set. Based on the information acquired from the operator, the rule engine determines an appropriate operating condition for the implantable cardiac stimulating device or a plurality of operating conditions from which the physician can choose. The system then displays the operating condition as a programming recommendation to the operator.

Preferably, the rule sets provide the operator with a list of adjustable parameters in an implantable device so that programming recommendations regarding any of a number of adjustable parameters in an implantable device can be obtained from the same decision support system.

The present invention also provides a decision support system which utilizes a patient/device database unit for storage of medical information of patients and operating parameters for various implantable cardiac stimulating devices. The patient/device database can also serve as a means for storage of the rule sets. The decision support system can thus retrieve some or all of the information required for generating a recommendation directly from the patient/device database and arrive at a programming recommendation.

Therefore, in accordance with the present invention a method for arriving at recommendations for programming of implantable cardiac stimulating devices is provided. The method involves selection of an appropriate rule set from a set of available rule sets according to information acquired from an operator or from a patient/device database. The operator is then engaged in a question and answer session wherein questions are posed according to the rules of the selected rule set and the operator's answers to previous questions. In this way, the operator goes through the rule set and upon completion of the session is presented with programming recommendations. Preferably, each recommendation is accompanied by comments, or citations from the medical literature, or both, describing the reasoning which led to the recommendation and references for further consultation by the operator.

The decision support system and method according to the present invention can be implemented as part of a cardiac stimulating device programmer. Thus, the present invention also provides an implantable device programmer capable of delivering programming guidance and decision support. The programmer is preferably capable of using the recommended operating condition to program an implantable cardiac stimulating device via a telemetry head. The programmer can also house a patient/device database unit as described above. Thus, an operator can access a patient's medical history and operating parameters for various implantable cardiac stimulating devices through the pro-

grammer's patient/device database, use the decision support feature of the programmer to determine an appropriate setting or operating condition, store the determined settings in the patient/device database, and engage the telemetric capabilities of the programmer to program the implantable device, in a single session with a device programmer according to the present invention.

5 Embodiments of the invention will now be described, by way of example, with reference to the drawings.

The above and other advantages of the invention will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which like reference numerals refer to like parts throughout, and in which:

10 FIG. 1 is a schematic diagram of a preferred embodiment of a decision support system in accordance with the present invention, in which a physician can access a patient/device database, use a rule engine to determine the optimal setting for an adjustable parameter in an implantable cardiac stimulating device, and program the device telemetrically;

15 FIG. 2 is a flow chart representing the structure and operation of a preferred embodiment of the decision support system in accordance with the present invention.

FIGS. 3 and 4 are a flow chart representing the structure of a preferred embodiment of a computer program controlling the operation of the decision support system in accordance with the present invention;

FIGS. 5 and 6 are a schematic representation of a preferred embodiment of a decision tree that can be used as a rule set for reaching a therapy recommendation in accordance with the present invention; and

20 FIG. 7 is a flow chart exemplifying the steps involved in reaching a therapy recommendation in accordance with the decision tree of FIGS. 5 and 6.

The present invention provides a decision support system 20, as shown in FIG. 1, that utilizes a central control unit 22 for the orchestration of tasks among a number of other units and components including a rule engine 24, a patient/device database 26, an input interface 28, an output interface 30, and a telemetry head 32. In addition, the rule engine 24 has access to a number of rule sets 34, stored in a memory unit 36. The control unit 22 is typically microprocessor-based and capable of performing multiple tasks. For example, as shown in FIG. 1, the control unit 22 communicates with an implantable cardiac stimulating device 38 through the telemetry head 32. The telemetry head 32 allows for bidirectional transfer of information. In one direction, the control unit 22 may receive information from the implantable cardiac stimulating device regarding the implantable device itself (e.g., name, model, current parameter settings, etc.) or regarding the operational history of the device and patient response to delivered therapy (e.g., date, energy, and cardiac activity of the patient following the last attempted therapy). In the other direction, the control unit 22 can transmit parameter settings or programming instructions to the implantable cardiac stimulating device and thus affect the operation of the device, if so desired. The implantable device could then stimulate cardiac tissue 40, according to the programmed instructions or parameters, through a conventional lead 42.

In order to determine the optimal parameter settings and programming instructions, the control unit 22 utilizes several auxiliary components. For example, an interface with the patient/device database 26 provides access to further detailed information about patients, and information about implantable devices, that may not be directly available from the implantable device 38. Such data may comprise the medical history of a patient, current drug regimen, and possible susceptibility to certain cardiac arrhythmias. The data may also include information such as guidelines provided by a manufacturer relating to specific device operations, available therapies, and lists of adjustable parameters and specifications for various devices. The data stored in the patient/device database 26 may relate to many different patients and many different implantable cardiac stimulating devices. Thus the decision support system 20 can be used in programming of a variety of different devices for many different patients.

45 As shown in FIG. 1, the patient/device database 26 may be implemented as part of the decision support system 20 using conventional data storage apparatus, such as a read-only memory cartridge, an optical disk drive, a hard disk drive, a floppy disk drive, a tape drive, or any other suitable data storage device. Alternatively, the database may be separate from the decision support system, as part of an accessory unit such as a mainframe computer in a hospital or any other central database (not shown).

50 The control unit 22 may also acquire information from the operator of the device such as a physician or a nurse, through the input interface 28. The input interface 28 can be a keyboard, a touch sensitive screen, a screen with a light pen, or any suitable interface that would allow the user to communicate with the control unit 22.

Messages and data can be displayed through the output interface 28, which may be a display monitor, a printer, or any other suitable apparatus for output of information.

55 The control unit 22 uses a rule engine 24, preferably at least partly microprocessor-based, to provide the operator with suggestions regarding the programming of the implantable device. Although FIG. 1 depicts the control unit 22 and the rule engine 24 as separate units of the decision support system, they can also be implemented with the same microprocessor. preferably, the rule engine 24 is flexible in that it can operate according to a variety of different rule

sets 34, corresponding to different implantable cardiac stimulating devices.

The rule sets 34 are stored in a memory unit 36, which may comprise a read-only memory cartridge, an optical disk drive, a hard disk drive, a floppy disk drive, a tape drive, or any other suitable data storage device. The rule engine 24 is linked to the memory unit 36 so that it can retrieve and load an appropriate rule set according to the instructions of control unit 22. The memory unit 36 may be implemented as part of the patient/device database 26.

FIGS. 2, 3 and 4 illustrate the decision support system of the present invention under control of a computer program. The program may be implemented in suitable microcode or any higher level computer language. In operation, the computer program causes the system to perform at least five basic tasks as shown schematically in FIG. 2. Initially, the system goes through a data gathering step 50, in which it acquires information regarding the patient (not shown) and the implantable cardiac stimulating device 40 (FIG. 1), that would be required for making a recommendation. Next, at a step 52, the system activates the rule engine 24 (FIG. 1) and, through the rule engine 24, selects an appropriate rule set 34 corresponding to the implantable cardiac stimulating device 40 that is to be programmed (FIG. 1). With the rule engine activated, the system proceeds to a step 54 at which point it guides the operator through an interactive question and answer session. At the step 54, the rule engine determines the questions posed to the operator according to the rule set 34 (FIG. 1) and based on the answers of the operator to previous questions. The session is continued until the rule engine 24 (FIG. 1) can provide a recommendation or set of recommendations from which the physician may choose. At that time, the system advances to a step 56 and displays the recommendation through the output interface 30 (FIG. 1). Any recommendation is preferably accompanied by a list of medical literature references upon which the recommendation is based.

Next, a test 58 is performed to determine whether the operator accepts the recommended setting for programming the device. A "yes" answer leads to a step 60 in which the telemetry head 32 (FIG. 1) is automatically activated and programming instructions are transmitted to the implantable cardiac stimulating device. A "no" answer at test 58, indicating that the operator is not satisfied with the recommendation, returns the system to the step 50 so that the operator can seek another recommendation. A loop encompassing the steps 50-56 and the test 58 can be repeated as many times as required until a satisfactory recommendation is obtained.

FIGS. 3 and 4 provide a more detailed description of the decision support system of this invention under control of a computer program. Here, the operator (not shown) would begin by choosing the mode in which the system is to acquire the desired information. First, at a test 62, the operator is provided with the choice of using the telemetric capabilities of the system to obtain information telemetrically from the implantable cardiac stimulating device 22 (FIG. 1). If so desired (answer "yes" to the test 62), then the system would activate the telemetry head 32 (FIG. 1) at a step 64 and access the memory (not shown) of the implantable cardiac stimulating device 38 (FIG. 1) at a step 66. Depending on the model and specifications of the implantable cardiac stimulating device 38 (FIG. 1), various pieces of information may be stored in its memory. Following step 66, the system would proceed to a step 72 to display the gathered information or, depending on the implementation, proceed to a step 70 to retrieve additional information from the database. This information may include technical information such as a list of parameter settings, or personal data on the patient, such as medical history, and recent cardiac activity as recorded by the device.

Alternatively, the operator may obtain information by accessing the patient/device database 26 (FIG. 1). To do this the system advances to a step 68 in response to a "no" answer to the test 62, and asks for the patient name or an identification number. This can be entered through the input interface 28 (FIG. 1). Having the name or the identification number of the patient, the system can search through the database 26 (FIG. 1) and retrieve whatever pertinent information is available in the database at step 70.

Regardless of the mode of information retrieval (telemetric or database-assisted), all of the gathered information is then displayed for the operator's perusal at step 72. (Alternatively, the operator could be asked to review and accept the data one piece at a time.) A test 74 is performed to determine if the operator finds the retrieved information sufficient and satisfactory. If the answer is "no" (for example, when the medical condition or drug regimen of the patient has changed since the last update of the patient/device database 26 (FIG. 1), or if the operator finds an error in the displayed record), then the system would move to a step 76 and begin to collect the correct and up-to-date information. Input of data by the operator can be facilitated using any known user-friendly data entry protocols. For example, the invention may be practiced using a mouse and menu bars, touch-sensitive screens, or pen-based computers.

Once the correct patient and device information have been gathered, the system activates the rule engine 24 (FIG. 1) at a step 78. The rule engine can then use this information at step 80 to select an appropriate rule set from one of the rule sets 34 (FIG. 1). As noted before, each rule set is marked in the system's memory 36 (FIG. 1) according to the implantable devices to which its rules apply. The appropriate rule set 34 (FIG. 1) may comprise a predefined decision tree, or alternatively, a multitude of interacting rules that are cross-referenced to each other in such a way that they can generate numerous different trees, depending on the order in which different rules are activated. The latter are commonly known as "deduction-oriented" rules or "antecedent-consequent" rule sets.

Regardless of the type of rule-set employed, the system then displays a list of parameters that can be adjusted in the implantable device at a step 82 (FIG. 4). The list is available either from the selected rule set --since each rule set

is defined for a particular implantable device -- or in an alternative embodiment from the patient/device database 26 (FIG. 1).

The operator is then asked to select, at a step 84, the parameter adjustment for which decision support is requested. (Alternatively, the system may select a default parameter adjustment, thereby not requiring a selection by the operator.) Following the operator's response, the system advances to an interactive question and answer step 86, led by the rule engine 24 (FIG. 1). The operator may select simply "yes" or "no" answers to certain questions or select from multiple-choice answers to others. Each question and possible answers to that question are displayed through the output interface 30 (FIG. 1). Each answer leads the rule engine 24 (FIG. 1) either to a new question, or to a recommendation. When a recommendation has been reached, it is displayed, together with the appropriate literature references, at a step 88. At a test 89, the operator is asked if he would like to review the answers that he had given at step 86 that caused the system to give the recommendation displayed. If the operator answers no, the system proceeds to a test 90. If the operator answers yes at test 89, the system proceeds to a test 87 and displays the answers given previously and asks if the operator would like to modify those answers. If the operator answers yes, the system returns to interactive question and answer step 86. (An additional step could be performed, wherein the operator is asked which answer he would like to modify and the interactive question and answer step 86 is restarted from the corresponding question.) If at test 87, the operator answers no, the system returns to test 89. If at test 89, the operator answered yes, test 90 is performed to determine whether the operator would like another recommendation -- either for the adjustment of another parameter, or based on different answers during the question and answer step 86. If the answer is "yes", then the system asks whether the current recommendation should be saved at a test 92. The system is capable of storing several recommendations or programming instructions, so that the operator can collect all the necessary recommendations before programming the implantable cardiac stimulating device 38 (FIG. 1). In this way, the system can avoid piecemeal programming of the implantable cardiac stimulating device 38 (FIG. 1) and it would allow the operator to adjust several parameters all at once. A "yes" answer to the test 92 advances the system to a step 94, at which point the current recommendation is saved, before returning to the step 82 to determine which parameter is to be adjusted next. A "no" answer to the test 92 returns the system to the step 82 directly.

A loop consisting of the steps 82-94 can be repeated until no other recommendations are required. At that point, a "no" response at the test 90 causes the system to proceed to a test 96 which determines whether the operator would like to program the implantable cardiac stimulating device 38 (FIG. 1) telemetrically. If so desired ("yes" answer), the system would automatically display the parameters that it plans to program and the recommended settings at a step 98. At this stage, the operator can use discretion to alter the recommendations of the decision support system before adjusting the implantable cardiac stimulating device 38 (FIG. 1) telemetrically. A test 100 is performed to allow for such alterations. If at test 100 the operator answers "yes", then the preferred settings can be entered at step 102 through the input interface 28 (FIG. 1). When the desired programming parameters have been set, the operator can initiate telemetric programming by entering a "no" answer at the test 100. This causes the system to activate telemetry head 32 (FIG. 1) at a step 104 and adjust the appropriate parameters at a step 106 according to the recommendation(s) made at the step 88.

The system then returns to the test 90 should the operator choose to adjust other parameters in the device, in which case the steps 92-88 are repeated. If not, the answers at tests 90 and 96 would be "no" which brings the program to an end.

To illustrate further a decision-making process of this invention, FIGS. 5 and 6 show a decision tree that can be used as one of the rule sets 34 (FIG. 1) in the programs represented in FIGS. 2, 3 and 4. This decision tree is an example of a rule set used for making recommendations in adjusting the pacing mode of an implantable pacemaker. However, it would be clear to those skilled in the art that similar decision trees can be easily constructed for adjustment of parameters other than for the pacing mode, and for programming of other implantable cardiac stimulating devices such as an implantable cardioverter- or an implantable cardioverter/defibrillator.

As seen in FIGS. 5 and 6, the decision tree provides a "multi-linear" rule set in which questions are organized in a hierarchical fashion. At each branching point or "node," the operator is presented either with a choice of yes/no answers (e.g., at a node 4, FIG. 5) or with multiple choices (e.g., at a node 5, FIG. 5). Each answer determines the next question, and ultimately leads to a recommendation at the outermost tips of the branches of the tree. In the tree of FIGS. 5 and 6, there are 62 such tips corresponding to 62 different recommendations for the adjustable pacing-mode parameter. The descent to each recommendation and the basis for the recommended pacing mode is described in detail in an attached Appendix. To illustrate further the decision making process,

FIG. 7 follows the progress of a hypothetical question-and-answer session along one of the branches of the decision tree in FIGS. 5 and 6. This branch corresponds to Mode Selection Conclusion 42 (see appendix). As shown in FIG. 7, the system begins by ascertaining whether the patient needs a pacemaker (node 120), whether the use of the pacemaker would be frequent (node 122), and if the patient is mentally competent (node 124). In this hypothetical case, the patient is a mentally competent subject with frequent need for a pacemaker due to an atrioventricular (AV) block. Therefore, the answers to the questions posed at the nodes 120, 122, and 124 are "yes", "no", and "no", respectively.

Although in this example the answers are provided by the operator, they can also be retrieved from the patient/device database 26 (FIG. 1) prior to the question-and-answer session. In that case, the system retrieves answers to as many questions as possible from the database, and then begins to ask for answers to the unanswered questions.

Following the answer to the question of the node 124, the system proceeds to inquire at a node 126 about the possibility of atrial fibrillation at a node 126. The node 126 is an example of a node which can lead to multiple (more than 2) sub-branches. In this case, the answer "none", indicating no evidence of atrial fibrillation, leads to a node 128 which, like the node 126, can lead to multiple sub-branches. When the sinus rhythm is normal, as is the case in the hypothetical example of FIG. 7, the system proceeds to nodes 130-134 to determine if there is possibility of AV block, a hypertrophied non-compliant ventricle, or evidence of pacemaker syndrome. Appropriate answers to these questions lead to a node 136 which determines if a separate sensor (not shown) for rate-responsive pacing should be activated, in case the sinus rate may exceed the maximum tracking rate. Since this is not a concern in this hypothetical case, the answer to the question of the node 136 is "no". At this point the system requires no further information for recommending a pacing-mode, and proceeds to recommend DDD (dual-chamber pacing and dual-chamber sensing with rate modulation due to atrial tracking) pacing mode for the hypothetical patient. Significantly, the recommendation is accompanied by a "comment" and "references" to scientific articles that explain the reasoning behind the recommendation, and provide the operator with original literature for further consultation.

As mentioned previously, the decision tree of FIGS. 5 and 6 provides a multi-linear rule set, which is to say that each of its conclusions (branch tips) is the result of specific answers to a set of questions arranged in a predetermined order. To generate such a tree, a set of questions are ordered, ideally from most general to most specific, and the system would lead the operator through the questions in that order. However, when multiple factors affect the operations of a device interdependently, as in the case for most implantable cardiac stimulating devices, the ranking of different questions becomes an exceedingly difficult and often subjective process. To overcome such problems, the rule sets may arrange a set of questions in an interdependent manner, such that each question appears not in a hierarchical order but depending on the history of the answers given previously.

Thus in some embodiments of the rule sets in accordance with this invention, the order in which questions are posed is neither predetermined nor linear. Such rule sets are well known (see, for example, P.H. Winston Artificial Intelligence 2nd Ed., Addison Wesley, pp, 166-204 (1984)) and can be implemented using programming subroutines in artificial intelligence (AI) shells based on any of the well known computer programming languages.

Thus, it is seen that a decision support system is provided that can aid physicians in selection and adjustment of appropriate parameters in implantable cardiac stimulating devices. This decision support system not only aids the physician in optimizing the operations of an implantable cardiac stimulating device, but also provides a bibliographic reference system to facilitate the decision making process. One skilled in the art will appreciate that the present invention can be practiced by other than the described embodiments, which are presented for purposes of illustration and not of limitation, and the present invention is limited only by the claims which follow.

APPENDIX

5

Mode Selection Conclusion 1

10

1. Does the patient need a pacemaker?  
Yes.

15

2. Will the patient's need for a pacemaker  
be infrequent?  
Yes.

20

3. Is the indication for pacing a  
neuroregulatory abnormality such as malignant vasovagal  
syncope or hypersensitive carotid sinus syndrome?  
Yes.

25

Recommended Mode: DDI

30

Comment: These patients usually have a  
vasodepressor component in addition to bradycardia.  
They need maintenance of atrial transport in addition to  
rate support but they do not require atrial pacing [1].

35

Reference [1]: Fitzpatrick, A. et al., "Dual-  
Chamber Pacing Aborts Vasovagal Syncope Induced by  
Headup 60° Tilt," Pace 1991; 14; 13-19.

40

Mode Selection Conclusion 2

45

1. Does the patient need a pacemaker?  
Yes.

50

2. Will the patient's need for a pacemaker  
be infrequent?  
Yes.

55

3. Is the indication for pacing a  
5 neuroregulatory abnormality such as malignant vasovagal  
syncope or hypersensitive carotid sinus syndrome?

No.

10 Recommended Mode: VVI with hysteresis

Comment: VVI with hysteresis will prevent asystole  
15 but otherwise prevent the pacemaker from interfering  
with the patient's intrinsic rhythm. The limitation of  
this mode is that it does not allow for progression of  
20 conduction system disease when pacing may be required  
frequently at which point restoration of AV synchrony or  
rate modulation may be of value for the patient.

25 Mode Selection Conclusion 3

1. Does the patient need a pacemaker?  
30 Yes.

2. Will the patient's need for a pacemaker  
be infrequent?  
35 No.

4. Is the patient mentally incompetent,  
40 unaware of surroundings, in need of continual nursing  
care, etc?  
Yes.

45 Recommended Mode: VVI

Comment: Despite the very limited functional  
50 status of the patient, one should carefully evaluate the  
effect of ventricular pacing on blood pressure and  
cardiac output. These patients may have pacemaker  
55 syndrome at which time, VVI pacing can worsen this  
clinical status, and despite their limited functional

5 existence, dual pacing may be necessary if pacing and therapy is recommended.

Mode Selection Conclusion 4

10 1. Does the patient need a pacemaker?  
Yes.

15 2. Will the patient's need for a pacemaker be infrequent?  
No.

20 4. Is the patient mentally incompetent, unaware of surroundings, in need of continual nursing care, etc?

25 No.

30 5. Is there evidence of Atrial fibrillation (None, Chronic, Intermittent)?  
Chronic.

35 6. Does the Ventricular rate increase with physiologic stress?  
Yes.

40 Recommended Mode: VVI Alternate: VVIR

45 Comment: While base rate pacing is all that is required at the time of implantation, progression of AV nodal conduction disease due to intrinsic pathologic processes or medications may render the patient chronotropically incompetent in the future. Rate modulated capability will allow for management of all options.

55 Mode Selection Conclusion 5

5                   1.    Does the patient need a pacemaker?  
                      Yes.

10                   2.    Will the patient's need for a pacemaker  
                      be infrequent?  
                      No.

15                   4.    Is the patient mentally incompetent,  
                      unaware of surroundings, in need of continual nursing  
                      care, etc?  
                      No.

20                   5.    Is there evidence of Atrial fibrillation  
                      (None, Chronic, Intermittent)?  
25                        Chronic.

30                   6.    Does the Ventricular rate increase with  
                      physiologic stress?  
                      No.

35                   Recommended Mode:    VVIR

40                   Comment:    In patients whose ventricular rate does  
                      not increase with stress, exercise tolerance will be  
                      improved with the addition of rate modulation [2].

45                   Given the chronic atrial fibrillation, the only  
                      option is single chamber ventricular pacing.

50                   Reference [2]: Humen, D.P. et al., "Activity-  
                      Sensing Rate-Responsive Pacing: Improvement in  
                      Myocardial Performance with Exercise," Pace, 1985; 8:  
55                        52-59.

5        Lau, C.P. et al., "Symptomology and Quality of Life  
in Patients with Rate-responsive Pacemaker: a Double-  
Blind Study," Clinical Cardiology, 1989; 12: 505-512.

10       Lau, C.P. et al., "Ventricular Rate-Adaptive Pacing  
in the Elderly," European Heart Journal, 1992; 13: 908-  
913.

15       Mode Selection Conclusion 6

1.     Does the patient need a pacemaker?  
      Yes.

20       2.     Will the patient's need for a pacemaker  
be infrequent?  
25       No.

30       4.     Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?  
      No.

35       5.     Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?  
      Intermittent.

40       7.     When is the pacemaker required?  
1.     During Atrial Fib.  
2.     Immediately after conversion (i.e.  
45       prolonged Sinus Node recovery  
time)  
3.     During Sinus rhythm due to marked  
50       bradycardia  
      1 only.

55       Recommended Mode:     DDI(R) Alternate:   VVI

Second alternative: VVIR

5

10

15

Comment: DDI(R): As the atrial fibrillation is intermittent, one might want to consider the DDI mode. This will not track the fibrillatory wave, but will provide back-up ventricular pacing support when AV Block is present during Atrial Fibrillation. During sinus rhythm, it will provide atrial pacing which may stabilize the atrial rhythm and prevent or minimize the episodes of fibrillation [3].

20

25

While base rate pacing is all that is required at the time of implantation, progression of AV nodal conduction disease due to intrinsic pathologic processes or medications may render the patient chronotropically incompetent in the future. Rate modulated capability will allow for management of all options.

30

For VVI: The patient only needs pacing during atrial fibrillation, hence for AV block at this time, the only mode which will be effective is VVI.

35

40

45

For VVIR: If the level of AV block is persistent during atrial fibrillation, consider a VVIR unit to improve exercise tolerance at these times. However, a VVIR may also increase its rate when the patient is in sinus rhythm, usurping control of the ventricle and induce pacemaker syndrome. The best mode to treat all options is DDIR.

50

Reference [3]: Bana, G. et al., "DDI Pacing in the Bradycardia-Tachycardia Syndrome," Pace, 1990; 13: 264-270.

55

Markewitz, A. et al., "What is the Most Appropriate Stimulation Mode in Patients with Sinus Node Dysfunction?" Pace, 1986; 9: 1115-1120.

5        Mode Selection Conclusion 7

1.    Does the patient need a pacemaker?  
      Yes.

10       2.    Will the patient's need for a pacemaker  
      be infrequent?

15                No.

20       4.    Is the patient mentally incompetent,  
      unaware of surroundings, in need of continual nursing  
      care, etc?

      No.

25       5.    Is there evidence of Atrial fibrillation  
      (None, Chronic, Intermittent)?

      Intermittent

30       7.    When is the pacemaker required?

      1.    During Atrial Fib.

35       2.    Immediately after conversion (i.e.  
      prolonged Sinus Node recovery time)

      3.    During Sinus rhythm due to marked  
      bradycardia

40                2 only.

45       8.    Is there a hypertrophied, non-compliant  
      ventricle?

      Yes.

50       12.   Is AV Block present or is the patient on  
      medications likely to cause AV Block?

      No.

55       Recommended Mode:    DDI Alternate:    DDIR

5           Comment: Although AV block is not present  
initially, pharmacologic therapy needed to control the  
ventricular response to the atrial fibrillation may  
unmask AV block, making single chamber AAI pacing  
unsafe. This same pharmacologic therapy may blunt  
10 chronotropic responsiveness warranting rate modulation.

15           Given the hypertrophied, non-compliant ventricle,  
one wants to maintain AV synchrony as much as possible  
when the atrium is NOT fibrillation. Hence VVI and VVIR  
are not appropriate in this setting.

20           While base rate pacing is all that is required at  
the time of implantation, progression of sinus or AV  
nodal conduction disease due to intrinsic pathologic  
25 processes or medications may render the patient  
chronotropically incompetent in the future. Rate  
modulated capability will allow for management of all  
30 options.

#### Mode Selection Conclusion 8

- 35           1. Does the patient need a pacemaker?  
Yes.
- 40           2. Will the patient's need for a pacemaker  
be infrequent?  
No.
- 45           4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?  
50 No.
- 55           5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

Intermittent.

5

7. When is the pacemaker required?

10

1. During Atrial Fib.

2. Immediately after conversion (i.e. prolonged Sinus Node recovery time)

3. During Sinus rhythm due to marked bradycardia

15

2 only.

20

8. Is there a hypertrophied, non-compliant ventricle?

Yes.

25

12. Is AV Block present or is the patient on medications likely to cause AV Block?

Yes.

30

Recommended Mode: DDI Alternate: DDDR

35

Comment: Pharmacologic therapy needed to control the ventricular response to the atrial fibrillation may exacerbate AV block, making single chamber AAI pacing unsafe. This same pharmacologic therapy may blunt chronotropic responsiveness warranting rate modulation.

40

45

50

As the atrial fibrillation is intermittent, one might want to consider the DDI mode. This will not track the fibrillatory wave, but will provide back-up ventricular pacing support when AV Block is present during atrial fibrillation. During sinus rhythm, it will provide atrial pacing which may stabilize the atrial rhythm and prevent or minimize episodes of fibrillation [3].

55

As the DDD mode tracks endogenous atrial activity, DDDR is the optimum mode but only when the MTR and MSR

can be independently programmed. A low MTR is chosen to  
5 minimize the rate increase when the atrial fibrillation.

During activity, a high MSR allows an appropriate  
increase in rate. In the absence of this capability,  
10 choose DDIR.

The only time the patient requires pacing is for  
protection against asystole episodes associated with the  
15 prolonged sinus node recovery time following conversion  
to MSR from atrial fibrillation. Given the concern  
about AV Block, dual chamber base rate pacing is  
recommended. However, this does not protect the patient  
20 against progression of disease or further compromise  
from required medications.

Given the hypertrophied, non-complaint ventricle,  
25 one wants to maintain AV synchrony as much as possible  
when the atrium is NOT fibrillation? Hence VVI and VVIR  
are not appropriate in this setting.  
30

While base rate pacing is all that is required at  
the time of implantation, progression of sinus or AV  
35 nodal conduction disease due to intrinsic pathologic  
processes or medications may render the patient  
chronotropically incompetent in the future. Rate  
40 modulated capability will allow for management of all  
options.

Reference [3]: Bana, G. et al., "DDI Pacing in the  
45 Bradycardia-Tachycardia Syndrome," Pace, 1990; 13: 264-  
270.

Markewitz, A. et al., "What is the Most Appropriate  
50 Stimulation Mode in Patients with Sinus Mode in Patients  
with Sinus Node Dysfunction?" Pace, 1986; 9: 1115-1120.

Mode Selection Conclusion 9

5

1. Does the patient need a pacemaker?  
Yes.

10

2. Will the patient's need for a pacemaker  
be infrequent?  
No.

15

4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

20

No.

25

5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?  
Intermittent.

30

7. When is the pacemaker required?

35

1. During Atrial Fib.
2. Immediately after conversion (i.e.  
prolonged Sinus Node recovery time)
3. During Sinus rhythm due to marked  
bradycardia
- 2 only.

40

8. Is there a hypertrophied, non-compliant  
ventricle?

45

No.

50

9. Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
cardiac output) with ventricular pacing or pre-pacing  
native rhythm when AV synchrony is lost?

55

Yes.

12. Is AV Block present or is the patient on  
medications likely to cause AV Block?

Yes.

10. Does Atrial rate increase with  
physiologic stress?

Yes.

Recommended Mode: DDI(R) Alternate: DDD(R)

Comment: The only time the patient requires pacing is for protection against asystole episodes associated with the prolonged sinus node recovery time following conversion to MSR from atrial fibrillation. Given the concern about AV Block, dual chamber base rate pacing is recommended. However, this does not protect the patient against progression of disease or further compromise from required medications [2].

Pharmacologic therapy needed to control the ventricular response to the atrial fibrillation may exacerbate AV block making single chamber AAI pacing unsafe. This same pharmacologic therapy may blunt chronotropic responsiveness warranting rate modulation.

The persistent sinus bradycardia requires both atrial pacing and rate modulation. As pharmacologic therapy to control the ventricular response to atrial fibrillation, dual chamber pacing in the form of DDIR will provide back-up ventricular support should AV block develop.

With documented pacemaker syndrome -- whether it be during ventricular pacing or its functional equivalent (a junctive rhythm with loss of AV synchrony, PVCs: with retrograde conduction) it is essential to maintain an appropriate atrio-ventricular contraction sequence [3].

5 While base rate pacing is all that is required at  
the time of implantation, progression of sinus or AV  
nodal conduction disease due to intrinsic pathologic  
10 processes or medications may render the patient  
chronotropically incompetent in the future. Rate  
modulated capability will allow for management of all  
options.

15 As the DDD mode tracks endogenous atrial activity,  
DDDR is the optimum mode but only when the MTR and MSR  
can be independently programmed. A low MTR is chosen to  
20 minimize the rate increase when inatrial fibrillation.  
During activity, a high MSR allows an appropriate  
increase in rate. In the absence of this capability,  
25 choose DDIR.

30 Reference [3]: Bana, G. et al., "DDI Pacing in the  
Bradycardia-Tachycardia Syndrome," Pace, 1990; 13: 264-  
270.

35 Markewitz, A. et al., "What is the Most Appropriate  
Stimulation Mode in Patients with Sinus Node  
Dysfunction?" Pace, 1986; 9: 1115-1120.

40 Reference [4]: Barold, S.S., "Cardiac Pacing  
Hemodynamics: The Pacemaker Syndrome," Cardio, 1991; 8:  
(Sept) 36-51.

45 Heldman, D. et al., "True Incidence of Pacemaker  
Syndrome," Pace, 1990; 13: 1742-1750.

50 Aussel, U., Furman, S., "The Pacemaker Syndrome,  
Ann (?) Internal Medicine," 1985; 103: 420-429.

55 Mode Selection Conclusion 10

- 5                   1.    Does the patient need a pacemaker?  
                    Yes.
- 10                   2.    Will the patient's need for a pacemaker  
be infrequent?  
                    No.
- 15                   4.    Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?  
                    No.
- 20                   5.    Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?  
25                      Intermittent.
- 30                   7.    When is the pacemaker required?  
                    1.    During Atrial Fib.  
                    2.    Immediately after conversion (i.e.  
                          prolonged Sinus Node recovery time)  
                    3.    During Sinus rhythm due to marked  
35                      bradycardia  
                    2 only.
- 40                   8.    Is there a hypertrophied, non-compliant  
ventricle?  
                    No.
- 45                   12. Is AV Block present or is the patient on  
medications likely to cause AV Block?  
                    Yes.
- 50                   10. Does Atrial rate increase with  
physiologic stress?  
55                      No.

5 Recommended Mode: DDIR Alternate: DDDR

10 Comment: The persistent sinus bradycardia requires both atrial pacing and rate modulation. As pharmacologic therapy to control the ventricular response to atrial fibrillation, dual chamber pacing in the form of DDIR will provide back-up ventricular support should AV block develop.

15 As the DDD mode tracks endogenous atrial activity, DDDR is the optimum mode but only when the MTR and MSR can be independently programmed. A low MTR is chosen to minimize the rate increase when inatrial fibrillation. During activity, a high MSR allows an appropriate increase in rate. In the absence of this capability, choose DDIR.

20 While base rate pacing is all that is required at the time of implantation, progression of AV nodal conduction disease due to intrinsic pathologic processes or medications may render the patient chronotropically incompetent in the future. Rate modulated capability will allow for management of all options.

30 Mode Selection Conclusion 11

- 35 1. Does the patient need a pacemaker?  
Yes.
- 40 2. Will the patient's need for a pacemaker be infrequent?  
No.
- 45 4. Is the patient mentally incompetent, unaware of surroundings, in need of continual nursing care, etc?

No.

5  
5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

Intermittent.

10  
7. When is the pacemaker required?

1. During Atrial Fib.

15  
2. Immediately after conversion (i.e.  
prolonged Sinus Node recovery time)

3. During Sinus rhythm due to marked  
bradycardia

20  
2 only.

8. Is there a hypertrophied, non-compliant  
25  
ventricle?

No.

30  
12. Is AV Block present or is the patient on  
medications likely to cause AV Block?

No.

35  
10. Does Atrial rate increase with  
physiologic stress?

Yes.

40  
Recommended mode: AAI Alternate: DDI

45  
Comment: The persistent sinus bradycardia requires  
both atrial pacing and rate modulation. As  
pharmacologic therapy to control the ventricular  
response to atrial fibrillation, dual chamber pacing in  
50  
the form of DDIR will provide back-up ventricular  
support should AV block develop.

55  
Mode Selection Conclusion 12

- 5                   1.    Does the patient need a pacemaker?  
                    Yes.
- 10                   2.    Will the patient's need for a pacemaker  
be infrequent?  
                    No.
- 15                   4.    Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?  
                    No.
- 20                   5.    Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?  
25                      Intermittent.
- 30                   7.    When is the pacemaker required?  
                    1.    During Atrial Fib.  
                    2.    Immediately after conversion (i.e.  
                          prolonged Sinus Node recovery time)  
                    3.    During Sinus rhythm due to marked  
35                           bradycardia  
                    2 only.
- 40                   8.    Is there a hypertrophied, non-compliant  
ventricle?  
                    No.
- 45                   12.   Is AV Block present or is the patient on  
medications likely to cause AV Block?  
                    No.
- 50                   10.   Does Atrial rate increase with  
physiologic stress?  
55                      No.

5 Recommended mode: AAIR Alternate: DDIR

10 Comment: The persistent sinus bradycardia requires  
both atrial pacing and rate modulation. As  
pharmacologic therapy to control the ventricular  
response to atrial fibrillation, dual chamber pacing in  
the form of DDIR will provide back-up ventricular  
15 support should AV block develop.

20 While base rate pacing is all that is required at  
the time of implantation, progression of AV nodal  
conduction disease due to intrinsic pathologic processes  
or medications may render the patient chronotropically  
incompetent in the future. Rate modulated capability  
25 will allow for management of all options.

Mode Selection Conclusion 13

30 1. Does the patient need a pacemaker?  
Yes.

35 2. Will the patient's need for a pacemaker  
be infrequent?  
No.

40 4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?  
45 No.

50 5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?  
Intermittent.

55 7. When is the pacemaker required?

- 5
1. During Atrial Fib.
  2. Immediately after conversion (i.e. prolonged Sinus Node recovery time)
  3. During Sinus rhythm due to marked bradycardia
- 10 1 and 2.

15 8. Is there a hypertrophied, non-compliant ventricle?

Yes.

20 12. Is AV Block present or is the patient on medications likely to cause AV Block?

Yes.

25 10. Does Atrial rate increase with physiologic stress?

Yes.

30 Recommended mode: DDDR Alternate: DDD

35 Comment: Despite the atrial fibrillation, the presence of AV block mandates DDD pacing. To minimize tracking the high rate during the atrial fibrillation but still allowing for an appropriate rate increase with exercise, choose DDDR in a system with independently programmable MTR and MSR.

40

45 As the DDD mode tracks endogenous atrial activity, DDDR is the optimum mode but only when the MTR and MSR can be independently programmed. A low MTR is chosen to minimize the rate increase when in atrial fibrillation. During activity, a high MSR allows an appropriate increase in rate. In the absence of this capability, choose DDIR.

50

55

Given the hypertrophied, non-compliant ventricle,  
one wants to maintain AV synchrony as much as possible  
when the atrium is NOT fibrillation. Hence VVI and VVIR  
are not appropriate in this setting.

Mode Selection Conclusion 14

1. Does the patient need a pacemaker?

Yes.

2. Will the patient's need for a pacemaker  
be infrequent?

No.

4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

No.

5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

Intermittent.

7. When is the pacemaker required?

1. During Atrial Fib.

2. Immediately after conversion (i.e.  
prolonged Sinus Node recovery time)

3. During Sinus rhythm due to marked  
bradycardia

1 and 2.

8. Is there a hypertrophied, non-compliant  
ventricle?

Yes.

12. Is AV Block present or is the patient on  
medications likely to cause AV Block?

Yes.

5  
10. Does Atrial rate increase with  
physiologic stress?

No.

10  
Recommended mode: DDDR

15       Comment: Despite the atrial fibrillation, the  
presence of AV block mandates DDD pacing. To minimize  
tracking the high rate during the atrial fibrillation  
but still allowing for an appropriate rate increase with  
20 exercise, choose DDDR in a system with independently  
programmable MTR and MSR.

25       As the DDD mode tracks endogenous atrial activity,  
DDDR is the optimum mode but only when the MTR and MSR  
can be independently programmed. A low MTR is chosen to  
30 minimize the rate increase when the atrial fibrillation.  
During activity, a high MSR allows an appropriate  
increase in rate. In the absence of this capability,  
choose DDIR.

35       Given the hypertrophied, non-compliant ventricle,  
one wants to maintain AV synchrony as much as possible  
40 when the atrium is NOT fibrillation. Hence VVI and VVIR  
are not appropriate in this setting.

45       Mode Selection Conclusion 15

1. Does the patient need a pacemaker?  
Yes.

50       2. Will the patient's need for a pacemaker  
be infrequent?

55       No.

5                   4.    Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

10                               No.

                  5.    Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

15                               Intermittent.

                  7.    When is the pacemaker required?

20                               1.    During Atrial Fib.

                              2.    Immediately after conversion (i.e.  
prolonged Sinus Node recovery time)

                              3.    During Sinus rhythm due to marked  
25                               bradycardia

                              1 and 2.

30                   8.    Is there a hypertrophied, non-compliant  
ventricle?

                              Yes.

35                   12.   Is AV Block present or is the patient on  
medications likely to cause AV Block?

                              No.

40                   10.   Does Atrial rate increase with  
physiologic stress?

45                               Yes.

Recommended mode:   DDI Alternate:   DDIR

50                   Comment:   The fact that pacing support is required  
during periods of atrial fibrillation indicating that  
there is some degree of VA block, even if only at very  
55                   rapid atrial rates at which time back-up ventricular

5 pacing is required. Thus AAI would not be appropriate  
in this setting.

10 As the atrial fibrillation is intermittent, one  
might want to consider the DDI mode. This will not  
track the fibrillatory wave, but will provide back-up  
ventricular pacing support when AV Block is present  
15 during atrial fibrillation. During sinus rhythm, it  
will provide atrial pacing which may stabilize the  
atrial rhythm and prevent or minimize the episodes of  
fibrillation [3].

20 Given the hypertrophied, non-compliant ventricle,  
one wants to maintain AV synchrony as much as possible  
when the atrium is NOT fibrillation. Hence VVI and VVIR  
25 are not appropriate in this setting.

30 While base rate pacing is all that is required at  
the time of implantation, progression of AV nodal  
conduction disease due to intrinsic pathologic processes  
or medications may render the patient chronotropically  
incompetent in the future. Rate modulated capability  
35 will allow for management of all options.

#### 40 Mode Selection Conclusion 16

1. Does the patient need a pacemaker?  
Yes.

45 2. Will the patient's need for a pacemaker  
be infrequent?  
No.

50 4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
55 care, etc?

No.

5

5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

10

Intermittent.

7. When is the pacemaker required?

15

1. During Atrial Fib.

2. Immediately after conversion (i.e.  
prolonged Sinus Node recovery time)

20

3. During Sinus rhythm due to marked  
bradycardia

1 and 2.

25

8. Is there a hypertrophied, non-compliant  
ventricle?

Yes.

30

12. Is AV Block present or is the patient on  
medications likely to cause AV Block?

No.

35

10. Does Atrial rate increase with  
physiologic stress?

No.

40

Recommended Mode: DDIR

45

Comment: The fact that pacing support is required  
during periods of atrial fibrillation indicating that  
there is some degree of VA block, even if only at very  
rapid atrial rates at which time back-up ventricular  
pacing is required. Thus AAI would not be appropriate  
in this setting.

50

55

As the atrial fibrillation is intermittent, one  
might want to consider the DDI mode. This will not

5 track the fibrillatory wave, but will provide back-up  
ventricular pacing support when AV Block is present  
during atrial fibrillation. During sinus rhythm, it  
will provide atrial pacing which may stabilize the  
atrial rhythm and prevent or minimize episodes of  
10 fibrillation.

15 Given the hypertrophied, non-compliant ventricle,  
one wants to maintain AV synchrony as much as possible  
when the atrium is NOT fibrillation. Hence VVI and VVIR  
are not appropriate in this setting.

20 Mode Selection Conclusion 17

25 1. Does the patient need a pacemaker?

Yes.

30 2. Will the patient's need for a pacemaker  
be infrequent?

No.

35 4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

No.

40 5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

Intermittent.

45 7. When is the pacemaker required?

1. During Atrial fib.

50 2. Immediately after conversion (i.e.  
prolonged Sinus Node recovery time)

3. During Sinus rhythm due to marked  
55 bradycardia

1 and 2.

5

8. Is there a hypertrophied, non-compliant ventricle?

No.

10

12. Is AV Block present or is the patient on medications likely to cause AV Block?

15

Yes.

10. Does Atrial rate increase with physiologic stress?

20

Yes.

Recommended Mode: DDD Alternate: DDDR

25

Comment: Despite the atrial fibrillation, presence of AV block mandates DDD pacing. To minimize tracking the high rate during the atrial fibrillation but still allowing for an appropriate rate increase with exercise, choose DDDR in a system with independently programmable MTR and MSR.

30

The only time the patient requires pacing is for protection against asystole episodes associated with the prolonged sinus node recovery time following conversion to MSR from atrial fibrillation. Given the concern about AV Block, dual chamber base rate pacing is recommended. However, this does not protect the patient against progression of disease or further compromise from required medications [3].

40

45

As the DDD mode tracks endogenous atrial activity, DDDR is the optimum mode but only when the MTR and MSR can be independently programmed. A low MTR is chosen to minimize the rate increase when in atrial fibrillation. During activity, a high MSR allows an appropriate

50

55

increase in rate. In the absence of this capability,  
choose DDIR.

While base rate pacing is all that is required at  
the time of implantation, progression of AV nodal  
conduction disease due to intrinsic pathologic processes  
or medications may render the patient chronotropically  
incompetent in the future. Rate modulated capability  
will allow for management of all options.

Reference [3]: Bana, G. et al., "DDI Pacing in the  
Bradycardia-Tachycardia Syndrome," Pace, 1990; 13: 264-  
270.

Markewitz, A. et al., "What is the Most Appropriate  
Stimulation Mode in Patients with Sinus Node  
Dysfunction?" Pace, 1986; 9: 1115-1120.

Mode Selection Conclusion 18

5

1. Does the patient need a pacemaker?  
Yes.

10

2. Will the patient's need for a pacemaker  
be infrequent?  
No.

15

4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

20

No.

25

5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?  
Intermittent.

30

7. When is the pacemaker required?

1. During Atrial fib.

35

2. Immediately after conversion (i.e.  
prolonged Sinus Node recovery time)

3. During Sinus rhythm due to marked  
bradycardia

40

1 and 2.

8. Is there a hypertrophied, non-compliant  
ventricle?

45

No.

50

12. Is AV Block present or is the patient on  
medications likely to cause AV Block?

Yes.

55

10. Does Atrial rate increase with  
physiologic stress?

No.

5 Recommended mode: DDDR

10 Comment: Despite the atrial fibrillation, presence  
of AV block mandates DDD pacing. To minimize tracking  
the high rate during the atrial fibrillation but still  
allowing for an appropriate rate increase with exercise,  
15 choose DDDR in a system with independently programmable  
MTR and MSR.

20 As the DDD mode tracks endogenous atrial activity,  
DDDR is the optimum mode but only when the MTR and MSR  
can be independently programmed. A low MTR is chosen to  
minimize the rate increase when in atrial fibrillation.

25 During activity, a high MSR allows an appropriate  
increase in rate. In the absence of this capability,  
choose DDIR.

30 Mode Selection Conclusion 19

35 1. Does the patient need a pacemaker?  
Yes.

40 2. Will the patient's need for a pacemaker  
be infrequent?  
No.

45 4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?  
No.

50 5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?  
55 Intermittent.

- 5                   7.    When is the pacemaker required?
1.    During Atrial fib.
2.    Immediately after conversion (i.e.  
prolonged Sinus Node recovery time)
- 10                  3.    During Sinus rhythm due to marked  
bradycardia
- 1 and 2.

- 15                  8.    Is there a hypertrophied, non-compliant  
ventricle?
- No.

- 20                  12.   Is AV Block present or is the patient on  
medications likely to cause AV Block?
- 25                  No.

10.   Does Atrial rate increase with  
physiologic stress?
- 30                  Yes.

Recommended mode:   DDI Alternate: DDDR

35                  Comment:   The fact that pacing support is required  
during periods of atrial fibrillation indicating that  
there is some degree of VA block, even if only at very  
40                  rapid atrial rates at which time back-up ventricular  
pacing is required. Thus AAI would not be appropriate  
in this setting.

45                  While base rate pacing is all that is required at  
the time of implantation, progression of sinus or AV  
nodal conduction disease due to intrinsic pathologic  
50                  processes or medications may render the patient  
chronotropically incompetent in the future. Rate  
modulated capability will allow for management of all  
55                  options.

Mode Selection Conclusion 20

5

1. Does the patient need a pacemaker?  
Yes.

10

2. Will the patient's need for a pacemaker  
be infrequent?

15

No.

20

4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

No.

25

5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?  
Intermittent.

30

7. When is the pacemaker required?

1. During Atrial fib.

35

2. Immediately after conversion (i.e.  
prolonged Sinus Node recovery time)

3. During Sinus rhythm due to marked  
bradycardia

40

- 1 and 2.

8. Is there a hypertrophied, non-compliant  
ventricle?

45

No.

50

12. Is AV Block present or is the patient on  
medications likely to cause AV Block?

No.

55

10. Does Atrial rate increase with  
physiologic stress?

No.

5 Recommended mode: AAIR Alternate: DDIR

10 Comment: As the DDD mode tracks endogenous atrial  
activity, DDDR is the optimum mode but only when the MTR  
and MSR can be independently programmed. A low MTR is  
15 chosen to minimize the rate increase when in atrial  
fibrillation. During activity, a high MSR allows an  
appropriate increase in rate. In the absence of this  
capability, choose DDIR.

20 While base rate pacing is all that is required at  
the time of implantation, progression of sinus or AV  
nodal conduction disease due to intrinsic pathologic  
25 processes or medications may render the patient  
chronotropically incompetent in the future. Rate  
modulated capability will allow for management of all  
options.

30

Mode Selection Conclusion 21

35 1. Does the patient need a pacemaker?  
Yes.

40 2. Will the patient's need for a pacemaker  
be infrequent?  
No.

45 4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

50 No.

55 5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

Intermittent.

5

7. When is the pacemaker required?

1. During Atrial fib.

10

2. Immediately after conversion (i.e.  
elongated Sinus Node recovery time)

3. During Sinus rhythm due to marked  
bradycardia

15

3 only.

8. Is there a hypertrophied, non-compliant  
ventricle? Yes.

20

10. Does Atrial rate increase with  
physiologic stress?

25

No.

Recommended mode: AAIR Alternate: DDIR

30

Comment: Given the hypertrophied, non-compliant  
ventricle, one wants to maintain AV synchrony as much as  
possible when the atrium is NOT fibrillation. Hence VVI  
and VVIR are not appropriate in this setting.

35

Mode Selection Conclusion 22

40

1. Does the patient need a pacemaker?  
Yes.

45

2. Will the patient's need for a pacemaker  
be infrequent?

No.

50

4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

55

No.

5                   5.   Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

Intermittent.

10

7.   When is the pacemaker required?

1.   During Atrial fib.

15

2.   Immediately after conversion (i.e.  
elongated Sinus Node recovery time)

3.   During Sinus rhythm due to marked  
bradycardia

20

3 only.

25

8.   Is there a hypertrophied, non-compliant  
ventricle?

No.

30

9.   Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
cardiac output) with ventricular pacing or pre-pacing  
native rhythm when AV synchrony is lost?

35

Yes.

40

10. Does Atrial rate increase with  
physiologic stress?

No.

45

Recommended mode:   AAIR Alternate:   DDIR

50

Comment:   With documented pacemaker syndrome -  
whether it be during ventricular pacing or its  
functional equivalent (a junctive rhythm with loss of AV  
synchrony, PVCs: with retrograde conduction) it is  
essential to maintain an appropriate atrio-ventricular  
contraction sequence [4].

55

5           Reference [4]: Barold, S.S., "Cardiac Pacing  
Hemodynamics: The Pacemaker Syndrome," Cardio, 1991;  
8: (Sept) 36-51.

10           Heldman, D. et al., "True Incidence of Pacemaker  
Syndrome," Pace, 1990; 13: 1742-1750.

15           Aussbel, U., Furman, S., "The Pacemaker Syndrome,  
Ann (?) Internal Medicine," 1985; 103: 420-429.

Mode Selection Conclusion 23

20           1.    Does the patient need a pacemaker?  
              Yes.

25           2.    Will the patient's need for a pacemaker  
be infrequent?  
              No.

30           4.    Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?  
35                No.

40           5.    Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?  
              Intermittent.

45           6.    Does the Ventricular rate increase with  
physiologic stress?  
              N/A.

50           7.    When is the pacemaker required?  
              1.    During Atrial fib.  
              2.    Immediately after conversion (i.e.  
55    elongated Sinus Node recovery time)

3. During Sinus rhythm due to marked  
bradycardia

3 only.

8. Is there a hypertrophied, non-compliant  
ventricle?

No.

9. Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
cardiac output) with ventricular pacing or pre-pacing  
native rhythm when AV synchrony is lost?

No.

10. Does Atrial rate increase with  
physiologic stress?

No.

Recommended mode: VVIR Alternate: DDIR

Mode Selection Conclusion 24

1. Does the patient need a pacemaker?  
Yes.

2. Will the patient's need for a pacemaker  
be infrequent?

No.

4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

No.

5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

Intermittent.

5

7. When is the pacemaker required?

1. During Atrial fib.

10

2. Immediately after conversion (i.e. elongated Sinus Node recovery time)

3. During Sinus rhythm due to marked bradycardia

15

3 only.

20

8. Is there a hypertrophied, non-compliant ventricle? Yes.

25

10. Does Atrial rate increase with physiologic stress?

Yes.

Recommended mode: AAI Alternate: DDI

30

35

Comment: Given the hypertrophied, non-compliant ventricle, one wants to maintain AV synchrony as much as possible when the atrium is NOT fibrillation. Hence VVI and VVIR are not appropriate in this setting.

Mode Selection Conclusion 25

40

1. Does the patient need a pacemaker?  
Yes.

45

2. Will the patient's need for a pacemaker be infrequent?  
No.

50

4. Is the patient mentally incompetent, unaware of surroundings, in need of continual nursing care, etc?

55

No.

5

5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

Intermittent.

10

7. When is the pacemaker required?

1. During Atrial fib.

15

2. Immediately after conversion (i.e.  
elongated Sinus Node recovery time)

3. During Sinus rhythm due to marked  
bradycardia

20

3 only.

25

8. Is there a hypertrophied, non-compliant  
ventricle?

No.

30

9. Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
cardiac output) with ventricular pacing or pre-pacing  
native rhythm when AV synchrony is lost?

35

Yes.

40

10. Does Atrial rate increase with  
physiologic stress?

Yes.

45

Recommended mode: AAI Alternate: DDI

50

Comment: With documented pacemaker syndrome -  
whether it be during ventricular pacing or its  
functional equivalent (a junctive rhythm with loss of AV  
synchrony, PVCS: with retrograde conduction) it is  
essential to maintain an appropriate atrio-ventricular  
contraction sequence [4].

55

5           Reference [4]: Barold, S.S., "Cardiac Pacing  
Hemodynamics: the Pacemaker Syndrome," Cardio, 1991; 8:  
(Sept) 36-51.

10           Heldman, D. et al., "True Incidence of Pacemaker  
Syndrome," Pace, 1990; 13: 1742-1750.

15           Aussel, U., Furman, S., "The Pacemaker Syndrome,  
Ann (?) Internal Medicine," 1985; 103: 420-429.

Mode Selection Conclusion 26

20           1.    Does the patient need a pacemaker?  
              Yes.

25           2.    Will the patient's need for a pacemaker  
be infrequent  
              No.

30           4.    Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?  
35                No.

40           5.    Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?  
              Intermittent.

45           7.    When is the pacemaker required?  
              1.    During Atrial fib.  
              2.    Immediately after conversion (i.e.  
50 elongated Sinus Node recovery time)  
              3.    During Sinus rhythm due to marked  
bradycardia  
              3 only.

5                   8.    Is there a hypertrophied, non-compliant  
ventricle?

                  No.

10                   9.    Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
cardiac output) with ventricular pacing or pre-pacing  
15 native rhythm when AV synchrony is lost?

                  No.

20                   10. Does Atrial rate increase with  
physiologic stress?

                  Yes.

25 Recommended mode:   VVI Alternate:   AAI, DDI

Mode Selection Conclusion 27

30                   1.    Does the patient need a pacemaker?  
                  Yes.

35                   2.    Will the patient's need for a pacemaker  
be infrequent?

                  No.

40                   4.    Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

45                   No.

50                   5.    Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

                  Intermittent.

55                   7.    When is the pacemaker required?

1. During Atrial fib.
- 5 2. Immediately after conversion (i.e. prolonged Sinus Node recovery time)
3. During Sinus rhythm due to marked bradycardia
- 10 1 and 3.
8. Is there a hypertrophied, non-compliant ventricle?
- 15 Yes.
12. Is AV Block present or is the patient on medications likely to cause AV Block?
- 20 Yes.
10. Does Atrial rate increase with physiologic stress?
- 25 Yes.

30 Recommended mode: DDD Alternate: DDDR

35 Comment: As the DDD mode tracks endogenous atrial activity, DDDR is the optimum mode but only when the MTR and MSR can be independently programmed. A low MTR is chosen to minimize the rate increase when in atrial fibrillation. During activity, a high MSR allows an appropriate increase in rate. In the absence of this capability, choose DDIR.

40

45 While base rate pacing is all that is required at the time of implantation, progression of sinus or AV nodal conduction disease due to intrinsic pathologic processes or medications may render the patient

50 chronotropically incompetent in the future. Rate modulated capability will allow for management of all options.

55

5           Given the hypertrophied, non-compliant ventricle,  
one wants to maintain AV synchrony as much as possible  
when the atrium is NOT fibrillation. Hence VVI and VVIR  
are not appropriate in this setting.

10           The fact that pacing support is required during  
periods of atrial fibrillation indicating that there is  
some degree of VA block, even if only at very rapid  
15           atrial rates at which time back-up ventricular pacing is  
required. Thus AAI would not be appropriate in this  
setting.

20

Mode Selection Conclusion 28

25           1. Does the patient need a pacemaker?  
Yes.

30           2. Will the patient's need for a pacemaker  
be infrequent?  
No.

35           4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?  
No.

40

5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?  
45           Intermittent.

7. When is the pacemaker required?  
1. During Atrial fib.  
50           2. immediately after conversion (i.e.  
prolonged Sinus Node recovery time)  
3. During Sinus rhythm due to marked  
55           bradycardia

1 and 3.

5

8. Is there a hypertrophied, non-compliant ventricle?

Yes.

10

12. Is AV Block present or is the patient on medications likely to cause AV Block? Yes.

15

10. Does Atrial rate increase with physiologic stress?

No.

20

Recommended mode: DDDR

25

Comment: Given the hypertrophied, non-compliant ventricle, one wants to maintain AV synchrony as much as possible when the atrium is NOT fibrillation. Hence VVI and VVIR are not appropriate in this setting.

30

Mode Selection Conclusion 29

35

1. Does the patient need a pacemaker?  
Yes.

40

2. Will the patient's need for a pacemaker be infrequent?  
No.

45

4. Is the patient mentally incompetent, unaware of surroundings, in need of continual nursing care, etc?

50

No.

55

5. Is there evidence of Atrial fibrillation (None, Chronic, Intermittent)?

Intermittent.

5

7. When is the pacemaker required?

1. During Atrial fib.

10

2. Immediately after conversion (i.e. prolonged Sinus Node recovery time)

3. During Sinus rhythm due to marked bradycardia

15

1 and 3.

8. Is there a hypertrophied, non-compliant ventricle?

20

Yes.

12. Is AV Block present or is the patient on medications likely to cause AV Block?

25

No.

10. Does Atrial rate increase with physiologic stress?

30

Yes.

Recommended mode: DDI Alternate: DDIR

35

Comment: Given the hypertrophied, non-compliant ventricle, one wants to maintain AV synchrony as much as possible when the atrium is NOT fibrillation. Hence VVI and VVIR are not appropriate in this setting.

40

While base rate pacing is all that is required at the time of implantation, progression of sinus or AV nodal conduction disease due to intrinsic pathologic processes or medications may render the patient chronotropically incompetent in the future. Rate modulated capability will allow for management of all options.

45

50

55

5           The fact that pacing support is required during  
periods of atrial fibrillation indicating that there is  
some degree of VA block, even if only at very rapid  
atrial rates at which time back-up ventricular pacing is  
10       required. Thus AAI would not be appropriate in this  
setting.

15       Mode Selection Conclusion 30

1.   Does the patient need a pacemaker?  
     Yes.
2.   Will the patient's need for a pacemaker  
     be infrequent?  
     No.
4.   Is the patient mentally incompetent,  
     unaware of surroundings, in need of continual nursing  
     care, etc?  
     No.
5.   Is there evidence of Atrial fibrillation  
     (None, Chronic, Intermittent)?  
     Intermittent.
7.   When is the pacemaker required?
  1.   During Atrial fib.
  2.   Immediately after conversion (i.e.  
45   prolonged Sinus Node recovery time)
  3.   During Sinus rhythm due to marked  
     bradycardia  
     1 and 3.
8.   Is there a hypertrophied, non-compliant  
     ventricle?

Yes.

5

12. Is AV Block present or is the patient on medications likely to cause AV Block?

No.

10

10. Does Atrial rate increase with physiologic stress?

No.

15

Recommended mode: DDIR

20

Comment: As the DDD mode tracks endogenous atrial activity, DDDR is the optimum mode but only when the MTR and MSR can be independently programmed. A low MTR is chosen to minimize the rate increase when in atrial fibrillation. During activity, a high MSR allows an appropriate increase in rate. In the absence of this capability, choose DDIR.

25

While base rate pacing is all that is required at the time of implantation, progression of AV nodal conduction disease due to intrinsic pathologic processes or medications may render the patient chronotropically incompetent in the future. A DDDR pacemaker will allow for management of all options.

30

Given the hypertrophied, non-compliant ventricle, one wants to maintain AV synchrony as much as possible when the atrium is NOT in fibrillation. Hence VVI and VVIR are not appropriate in this setting.

35

The fact that pacing support is required during periods of atrial fibrillation indicating that there is some degree of VA block, even if only at very rapid atrial rates at which time back-up ventricular pacing is

40

required. Thus AAI would not be appropriate in this setting.

Mode Selection Conclusion 31

- 10                   1. Does the patient need a pacemaker?  
                    Yes.
- 15                   2. Will the patient's need for a pacemaker  
be infrequent?  
                    No.
- 20                   4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?  
25                      No.
5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?  
30                      Intermittent.
7. When is the pacemaker required?  
35                      1. During Atrial fib.  
                    2. Immediately after conversion (i.e.  
prolonged Sinus Node recovery time)  
40                      3. During Sinus rhythm due to marked  
bradycardia  
                    1 and 3.
- 45                   8. Is there a hypertrophied, non-compliant  
ventricle?  
                    No.
- 50                   9. Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
cardiac output) with ventricular pacing or pre-pacing  
55                    native rhythm when AV synchrony is lost?

Yes.

5

12. Is AV Block present or is the patient on medications likely to cause AV Block?

Yes.

10

10. Does Atrial rate increase with physiologic stress?

Yes.

15

Recommended mode: DDDR

20

Comment: As the DDD mode tracks endogenous atrial activity, DDDR is the optimum mode but only when the MTR and MSR can be independently programmed. A low MTR is chosen to minimize the rate increase when in atrial fibrillation. During activity, a high MSR allows an appropriate increase in rate. In the absence of this capability, choose DDIR.

25

With documented pacemaker syndrome - whether it being during ventricular pacing or its functional equivalent (a junctive rhythm with loss of AV synchrony, PVC: with retrograde conduction) it is essential to maintain an appropriate atrio-ventricular contraction sequence [4].

30

Reference [4]: Barold, S.S. "Cardiac Pacing Hemodynamics: The Pacemaker Syndrome," Cardio, 1991; 8: (Sept) 36-51.

35

Heldman, D. et al., "True Incidence of Pacemaker Syndrome," Pace, 1990; 13: 1742-1750.

40

Aussel, U., Furman, S., "The Pacemaker Syndrome, Ann (?) Internal Medicine," 1985; 103: 420-429.

45

Mode Selection Conclusion 32

5

1. Does the patient need a pacemaker?  
Yes.

10

2. Will the patient's need for a pacemaker  
be infrequent?  
No.

15

4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

20

No.

25

5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?  
Intermittent.

30

7. When is the pacemaker required?

1. During Atrial fib.

2. Immediately after conversion (i.e.

35

prolonged Sinus Node recovery time)

3. During Sinus rhythm due to marked

bradycardia

1 and 3.

40

8. Is there a hypertrophied, non-compliant  
ventricle?

45

No.

50

9. Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
cardiac output) with ventricular pacing or pre-pacing  
native rhythm when AV synchrony is lost?

Yes.

55

12. Is AV Block present or is the patient on medications likely to cause AV Block?

Yes.

10. Does Atrial rate increase with physiologic stress?

No.

Recommended mode: DDDR

Comment: As the DDD mode tracks endogenous atrial activity, DDDR is the optimum mode but only when the MTR and MSR can be independently programmed. A low MTR is chosen to minimize the rate increase when in atrial fibrillation. During activity, a high MSR allows an appropriate increase in rate. In the absence of this capability, choose DDIR.

With documented pacemaker syndrome - whether it being during ventricular pacing or its functional equivalent (a junctive rhythm with loss of AV synchrony, PVC: with retrograde conduction) it is essential to maintain an appropriate atrio-ventricular contraction sequence [4].

Reference [4]: Barold, S.S., "Cardiac Pacing Hemodynamics: the Pacemaker Syndrome," Cardio, 1991; 8: (Sept) 36-51.

Heldman, D. et al., "True Incidence of Pacemaker Syndrome," Pace, 1990; 13: 1742-1750.

Aussel, U., Furman, S., "The Pacemaker Syndrome, Ann (?) Internal Medicine," 1985; 103: 420-429.

Mode Selection Conclusion 33

- 5                   1.    Does the patient need a pacemaker?  
                    Yes.
- 10                   2.    Will the patient's need for a pacemaker  
be infrequent?  
                    No.
- 15                   4.    Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?  
                    No.
- 20                   5.    Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?  
25                      Intermittent.
- 30                   7.    When is the pacemaker required?  
                    1.    During Atrial fib.  
                    2.    Immediately after conversion (i.e.  
prolonged Sinus Node recovery time)  
35                      3.    During Sinus rhythm due to marked  
bradycardia  
                    1 and 3.
- 40                   8.    Is there a hypertrophied, non-compliant  
ventricle?  
                    No.
- 45                   9.    Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
cardiac output) with ventricular pacing or pre-pacing  
50                      native rhythm when AV synchrony is lost?  
                    Yes.
- 55

12. Is AV Block present or is the patient on medications likely to cause AV Block?

No.

10. Does Atrial rate increase with physiologic stress?

Yes.

Recommended mode: DDI Alternate: DDIR or DDDR

Comment: As the DDD mode tracks endogenous atrial activity, DDDR is the optimum mode but only when the MTR and MSR can be independently programmed. A low MTR is chosen to minimize the rate increase when in atrial fibrillation. During activity, a high MSR allows an appropriate increase in rate. In the absence of this capability, choose DDIR.

With documented pacemaker syndrome - whether it being during ventricular pacing or its functional equivalent (a junctive rhythm with loss of AV synchrony, PVC: with retrograde conduction) it is essential to maintain an appropriate atrio-ventricular contraction sequence [4].

While base rate pacing is all that is required at the time of implantation, progression of sinus or AV nodal conduction disease due to intrinsic pathologic processes or medications may render the patient chronotropically incompetent in the future. Rate modulated capability will allow for management of all options.

Reference [4]: Barold, S.S., "Cardiac Pacing Hemodynamics: The Pacemaker Syndrome," Cardio, 1991; 8: (Sept) 36-51.

Heldman, D. et al., "True Incidence of Pacemaker  
Syndrome," Pace, 1990; 13: 1742-1750.

Aussbel, U., Furman, S., "The Pacemaker Syndrome,  
Ann (?) Internal Medicine," 1985; 103: 420-429.

Mode Selection Conclusion 34

1. Does the patient need a pacemaker?  
Yes.

2. Will the patient's need for a pacemaker  
be infrequent?

No.

4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

No.

5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

Intermittent.

7. When is the pacemaker required?

1. During Atrial fib.

2. Immediately after conversion (i.e.  
prolonged Sinus Node recovery time)

3. During Sinus rhythm due to marked  
bradycardia

1 and 3.

8. Is there a hypertrophied, non-compliant  
ventricle?

No.

5           9.    Is there evidence of pacemaker syndrome  
          (fall in blood pressure, retrograde conduction, fall in  
          cardiac output) with ventricular pacing or pre-pacing  
          native rhythm when AV synchrony is lost?

10                   Yes.

          12.   Is AV Block present or is the patient on  
          medications likely to cause AV Block?

15                   No.

          10.   Does Atrial rate increase with  
20           physiologic stress?

                  No.

25           Recommended mode:    DDIR

30           Comment:   With documented pacemaker syndrome -  
          whether it being during ventricular pacing or its  
          functional equivalent (a junctive rhythm with loss of AV  
          synchrony, PVC: with retrograde conduction) it is  
          essential to maintain an appropriate atrio-ventricular  
35           contraction sequence [4].

40           The fact that pacing support is required during  
          periods of atrial fibrillation indicating that there is  
          some degree of VA block, even if only at very rapid  
          atrial rates at which time back-up ventricular pacing is  
          required. Thus AAI would not be appropriate in this  
45           setting.

50           Reference [4]: Barold, S.S., "Cardiac Pacing  
          Hemodynamics: The Pacemaker Syndrome," Cardio, 1991; 8:  
          (Sept) 36-51.

55           Heldman, D. et al., "True Incidence of Pacemaker  
          Syndrome," Pace, 1990; 13: 1742-1750.

Aussel, U., Furman, S., "The Pacemaker Syndrome,  
Ann (?) Internal Medicine," 1985; 103: 420-429.

Mode Selection Conclusion 35

1. Does the patient need a pacemaker?  
Yes.

2. Will the patient's need for a pacemaker  
be infrequent?  
No.

4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?  
No.

5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?  
Intermittent.

7. When is the pacemaker required?  
1. During Atrial fib.  
2. Immediately after conversion (i.e.  
prolonged Sinus Node recovery time)  
3. During Sinus rhythm due to marked  
bradycardia  
1 and 3.

8. Is there a hypertrophied, non-compliant  
ventricle?  
No.

9. Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in

cardiac output) with ventricular pacing or pre-pacing native rhythm when AV synchrony is lost?

No.

10. Does Atrial rate increase with physiologic stress?

Yes.

Recommended mode: DDI Alternate: DDIR

Comment: While base rate pacing is all that is required at the time of implantation, progression of sinus or AV nodal conduction disease due to intrinsic pathologic processes or medications may render the patient chronotropically incompetent in the future. Rate modulated capability will allow for management of all options.

The fact that pacing support is required during periods of atrial fibrillation indicating that there is some degree of VA block, even if only at very rapid atrial rates at which time back-up ventricular pacing is required. Thus AAI would not be appropriate in this setting.

Mode Selection Conclusion 36

1. Does the patient need a pacemaker?

Yes.

2. Will the patient's need for a pacemaker be infrequent?

No.

4. Is the patient mentally incompetent, unaware of surroundings, in need of continual nursing care, etc?

No.

5                   5.    Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

Intermittent.

10                   7.    When is the pacemaker required?

1.    During Atrial fib.

15                   2.    Immediately after conversion (i.e.  
prolonged Sinus Node recovery time)

3.    During Sinus rhythm due to marked  
bradycardia

20                               1 and 3.

                  8.    Is there a hypertrophied, non-compliant  
ventricle?

25                               No.

                  9.    Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
30                   cardiac output) with ventricular pacing or pre-pacing  
native rhythm when AV synchrony is lost?

35                               No.

                  10.   Does Atrial rate increase with  
physiologic stress?

40                               Yes.

Recommended mode:   DDI Alternate: DDIR

45                               Comment: While base rate pacing is all that is  
required at the time of implantation, progression of  
sinus or AV nodal conduction disease due to intrinsic  
50                   pathologic processes or medications may render the  
patient chronotropically incompetent in the future.  
Rate modulated capability will allow for management of  
55                   all options.

The fact that pacing support is required during periods of atrial fibrillation indicating that there is some degree of VA block, even if only at very rapid atrial rates at which time back-up ventricular pacing is required. Thus AAI would not be appropriate in this setting.

Mode Selection Conclusion 37

1. Does the patient need a pacemaker?  
Yes.

2. Will the patient's need for a pacemaker be infrequent?

No.

4. Is the patient mentally incompetent, unaware of surroundings, in need of continual nursing care, etc?

No.

5. Is there evidence of Atrial fibrillation (None, Chronic, Intermittent)?

None.

11. What is the status of the sinus rhythm (Neuroregulatory abnormality, Normal, Sinus Node dysfunction)?

Neuroregulatory abnormality.

Recommended mode: DDI

Comment: A neuroregulatory abnormality causes syncope by one of two mechanisms. It inhibits the cardiac rate (both sinus slowing and AV block) and causes vasodilation. Pure cardioinhibitory effects can

be treated with VVI pacing. More often, there is a combined mechanism at which time the vasodilation requires AV synchrony to minimize the hypotensive episodes. These patients do not require atrial pacing - hence DDI mode [1].

Reference [ 1 ]: Fitzpatrick, A. et al., "Dual-Chamber Pacing Aborts Vasovagal Syncope Induced by Headup 600 Tilt," Pace 1991; 14: 13-19.

Mode Selection Conclusion 38

1. Does the patient need a pacemaker?  
Yes.

2. Will the patient's need for a pacemaker be infrequent?  
No.

4. Is the patient mentally incompetent, unaware of surroundings, in need of continual nursing care, etc?  
No.

5. Is there evidence of Atrial fibrillation (None, Chronic, Intermittent)?  
None.

11. What is the status of the sinus rhythm (Neuroregulatory abnormality, Normal, Sinus Node dysfunction)?  
Normal.

12. Is AV Block present or is the patient on medications likely to cause AV Block?  
No.

Recommended mode: Reconsider need for pacemaker.

5                   Comment: Although the initial decision is that the  
patient required a pacemaker, based on the answers,  
10 there is no evidence for even intermittent sinus node  
dysfunction or AV block. Unless the pacemaker is being  
implanted prophylactically in which case answer the  
15 questions as if the reason for the pacemaker were  
manifest; reconsider the decision for permanent cardiac  
pacing.

20 Mode Selection Conclusion: 39

1. Does the patient need a pacemaker?  
Yes.

25 2. Will the patient's need for a pacemaker  
be infrequent?

30 No.

4. Is the patient mentally incompetent,  
35 unaware of surroundings, in need of continual nursing  
care, etc?

No.

40 5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

None.

45 11. What is the status of the sinus rhythm  
(Neuroregulatory abnormality, Normal, Sinus Node  
dysfunction)?

50 Normal.

55 12. Is AV Block present or is the patient on  
medications likely to cause AV Block?

Yes.

5                   8.    Is there a hypertrophied, non-compliant  
ventricle?

Yes.

10                   13.   Is the sinus rate likely to exceed the  
maximum tracking rate?

Yes.

15  
Recommended mode:    DDDR Alternate: DDD

20                   Comment: Although sinus node function may be  
normal, if the sinus rate exceeds the MTR, the patient  
may be limited by the loss of appropriate AV synchrony  
25                   during normal upper rate behavior. Choosing DDDR will  
allow for sensor-driven rate smoothing [5].

30                   Given the hypertrophied, non-compliant ventricle,  
one wants to maintain AV synchrony as much as possible  
when the atrium is NOT fibrillation. Hence VVI and VVIR  
are not appropriate in this setting.

35                   Reference [5]: Higano, S. T., Hayes, D. L., Elsinger,  
G., "Sensor-Driven Rate Smoothing in a DDDR Pacemaker,"  
40                   Pace, 1989; 12: 922-929.

40                   Mode Selection Conclusion 40

45                   1.    Does the patient need a pacemaker?  
Yes.

50                   2.    Will the patient's need for a pacemaker  
be infrequent?

No.

55

4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

No.

5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

None.

11. What is the status of the sinus rhythm  
(Neuroregulatory abnormality, Normal, Sinus Node  
dysfunction)?

Normal.

12. Is AV Block present or is the patient on  
medications likely to cause AV Block?

Yes.

8. Is there a hypertrophied, non-compliant  
ventricle?

Yes.

13. Is the sinus rate likely to exceed the  
maximum tracking rate?

No.

Recommended mode: DDD

Comment: Given the hypertrophied, non-compliant  
ventricle, one wants to maintain AV synchrony as much as  
possible when the atrium is NOT fibrillation. Hence  
VVI and VVIR are not appropriate in this setting.

Mode Selection Conclusion 41

5

1. Does the patient need a pacemaker?  
Yes.

10

2. Will the patient's need for a pacemaker  
be infrequent?

No.

15

4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

20

No.

25

5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

None.

30

11. What is the status of the sinus rhythm  
(Neuroregulatory abnormality, Normal, Sinus Node  
dysfunction)?

35

Normal.

40

12. Is AV Block present or is the patient on  
medications likely to cause AV Block?

Yes.

45

8. Is there a hypertrophied, non-compliant  
ventricle?

No.

50

9. Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
cardiac output) with ventricular pacing or pre-pacing  
native rhythm when AV synchrony is lost?

55

Yes.

5                   13. Is the sinus rate likely to exceed the  
maximum tracking rate?

Yes.

10                   Recommended mode: DDDR Patient Disc:

15                   Comment: With documented pacemaker syndrome -  
whether it being during ventricular pacing or its  
functional equivalent (a junctive rhythm with loss of AV  
synchrony, PVC: with retrograde conduction) it is  
20                   essential to maintain an appropriate atrio-ventricular  
contraction sequence [4].

25                   Reference [4]: Barold, S.S., "Cardiac Pacing  
Hemodynamics: The Pacemaker Syndrome," Cardio, 1991; 8:  
(Sept) 36-51.

30                   Heldman, D. et al., "True Incidence of Pacemaker  
Syndrome," Pace, 1990; 13: 1742-1750.

35                   Aussbel, U., Furman, S., "The Pacemaker Syndrome, Ann  
(?) Internal Medicine," 1985; 103: 420-429,

40                   Mode Selection Conclusion 42

1. Does the patient need a pacemaker?  
Yes.

45                   2. Will the patient's need for a pacemaker  
be infrequent?

50                   No.

55                   4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

No.

5                   5.    Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

None.

10                   11.   What is the status of the sinus rhythm  
(Neuroregulatory abnormality, Normal, Sinus Node  
dysfunction)?

15                               Normal.

20                   12.   Is AV Block present or is the patient on  
medications likely to cause AV Block?

Yes.

25                   8.    Is there a hypertrophied, non-compliant  
ventricle?

No.

30                   9.    Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
cardiac output) with ventricular pacing or pre-pacing  
35    native rhythm when AV synchrony is lost?

Yes.

40                   13.   Is the sinus rate likely to exceed the  
maximum tracking rate?

No.

45    Recommended mode:               DDD

Patient Disc:

50                   Comment:   With documented pacemaker syndrome -  
whether it being during ventricular pacing or its  
functional equivalent (a junctive rhythm with loss of AV  
55    synchrony, PVC: with retrograde conduction) it is

essential to maintain an appropriate atrio-ventricular contraction sequence [4].

Reference [4]: Barold, S.S., "Cardiac Pacing Hemodynamics: The Pacemaker Syndrome," Cardio, 1991; 8: (Sept) 36-51.

Heldman, D. et al., "True Incidence of Pacemaker Syndrome," Pace, 1990; 13: 1742-1750.

Aussel, U., Furman, S., "The Pacemaker Syndrome, Ann (?) Internal Medicine," 1985; 103: 420-429.

Mode Selection Conclusion 43

1. Does the patient need a pacemaker?  
Yes.

2. Will the patient's need for a pacemaker be infrequent?  
No.

4. Is the patient mentally incompetent, unaware of surroundings, in need of continual nursing care, etc?  
No.

5. Is there evidence of Atrial fibrillation (None, Chronic, Intermittent)?  
None.

11. What is the status of the sinus rhythm (Neuroregulatory abnormality, Normal, Sinus Node dysfunction)?  
Normal.

12. Is AV Block present or is the patient on medications likely to cause AV Block?

Yes.

8. Is there a hypertrophied, non-compliant ventricle?

No.

9. Is there evidence of pacemaker syndrome (fall in blood pressure, retrograde conduction, fall in cardiac output) with ventricular pacing or pre-pacing native rhythm when AV synchrony is lost?

No.

13. Is the sinus rate likely to exceed the maximum tracking rate?

Yes.

Recommended mode: DDDR

Mode Selection Conclusion 44

1. Does the patient need a pacemaker?

Yes.

2. Will the patient's need for a pacemaker be infrequent?

No.

4. Is the patient mentally incompetent, unaware of surroundings, in need of continual nursing care, etc?

No.

5. Is there evidence of Atrial fibrillation (None, Chronic, Intermittent)?

None.

5                    11. What is the status of the sinus rhythm  
(Neuroregulatory abnormality, Normal, Sinus Node  
dysfunction)?

10                    Normal.

                  12. Is AV Block present or is the patient on  
medications likely to cause AV Block?

15                    Yes.

                  8. Is there a hypertrophied, non-compliant  
ventricle?

20                    No.

                  9. Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
cardiac output) with ventricular pacing or pre-pacing  
native rhythm when AV synchrony is lost?

30                    No.

                  13. Is the sinus rate likely to exceed the  
maximum tracking rate?

35                    No.

Recommended mode:    DDD

40

Mode Selection Conclusion 45

45                    1. Does the patient need a pacemaker?  
Yes.

                  2. Will the patient's need for a pacemaker  
be infrequent?

50                    No.

55

5                   4.    Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

                  No.

10                   5.    Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

                  None.

15                   11.   What is the status of the sinus rhythm  
(Neuroregulatory abnormality, Normal, Sinus Node  
dysfunction)?

20                   Sinus Node dysfunction.

25                   12.   Is AV Block present or is the patient on  
medications likely to cause AV Block?

                  No.

30                   10.   Does Atrial rate increase with  
physiologic stress?

                  No.

35                   8.    Is there a hypertrophied, non-compliant  
ventricle?

                  Yes.

40                   14.   Is AV node function normal even at higher  
rates?

                  Yes.

45                   Recommended mode:   AAIR

50                   Comment: Given the hypertrophied, non-compliant  
ventricle, one wants to maintain AV synchrony as much as  
possible when the atrium is NOT fibrillation. Hence VVI  
and VVIR are not appropriate in this setting.

Mode Selection Conclusion 46

5

1. Does the patient need a pacemaker?

Yes.

10

2. Will the patient's need for a pacemaker  
be infrequent?

No.

15

4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

20

No.

25

5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

None.

30

11. What is the status of the sinus rhythm  
(Neuroregulatory abnormality, Normal, Sinus Node  
dysfunction)?

35

Sinus Node dysfunction.

40

12. Is AV Block present or is the patient on  
medications likely to cause AV Block?

No.

45

10. Does Atrial rate increase with  
physiologic stress?

No.

50

8. Is there a hypertrophied, non-compliant  
ventricle?

Yes.

55

14. Is AV node function normal even at higher rates?

No.

Recommended mode: DDIR

Comment: Given the hypertrophied, non-compliant ventricle, one wants to maintain AV synchrony as much as possible when the atrium is NOT fibrillation. Hence VVI and VVIR are not appropriate in this setting.

Mode Selection Conclusion 47

1. Does the patient need a pacemaker?  
Yes.

2. Will the patient's need for a pacemaker be infrequent?

No.

4. Is the patient mentally incompetent, unaware of surroundings, in need of continual nursing care, etc?

No.

5. Is there evidence of Atrial fibrillation (None, Chronic, Intermittent)?

None.

11. What is the status of the sinus rhythm (Neuroregulatory abnormality, Normal, Sinus Node dysfunction)?

Sinus Node dysfunction.

12. Is AV Block present or is the patient on medications likely to cause AV Block?

No.

5                   10. Does Atrial rate increase with  
physiologic stress?

No.

10                   8. Is there a hypertrophied, non-compliant  
ventricle?

No.

15                   9. Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
20 cardiac output) with ventricular pacing or pre-pacing  
native rhythm when AV synchrony is lost?

Yes.

25                   14. Is AV node function normal even at higher  
rates?

Yes.

30  
Recommended mode: AAIR Patient Disc:

35                   Comment: With documented pacemaker syndrome  
whether it being during ventricular pacing or its  
functional equivalent (a junctive rhythm with loss of AV  
synchrony, PVC: with retrograde conduction) it is  
40 essential to maintain an appropriate atrio-ventricular  
contraction sequence [4].

45                   Reference [4]: Barold, S.S., "Cardiac Pacing  
Hemodynamics: The Pacemaker Syndrome," Cardio, 1991;  
8: (Sept) 36-51.

50                   Heldman, D. et al., "True Incidence of Pacemaker  
Syndrome," Pace, 1990; 13: 1742-1750.

55

Aussbel, U., Furman, S., "The Pacemaker Syndrome, Ann  
(?) Internal Medicine," 1985; 103: 420-429.

5

Mode Selection Conclusion 48

10

1. Does the patient need a pacemaker?  
Yes.

15

2. Will the patient's need for a pacemaker  
be infrequent?  
No.

20

4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

25

No.

30

5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?  
None.

35

11. What is the status of the sinus rhythm  
(Neuroregulatory abnormality, Normal, Sinus Node  
dysfunction)?

Sinus Node dysfunction-

40

12. Is AV Block present or is the patient on  
medications likely to cause AV Block?  
No.

45

10. Does Atrial rate increase with  
physiologic stress?  
No.

50

8. Is there a hypertrophied, non-compliant  
ventricle?

55

No.

5                   9.    Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
cardiac output) with ventricular pacing or pre-pacing  
10 native rhythm when AV synchrony is lost?

Yes.

15                   14.   Is AV node function normal even at higher  
rates?

No.

20 Recommended mode:   DDIR Patient Disc:

25                   Comment:   With documented pacemaker syndrome  
whether it being during ventricular pacing or its  
functional equivalent (a junctive rhythm with loss of AV  
synchrony, PVC: with retrograde conduction) it is  
essential to maintain an appropriate atrio-ventricular  
30 contraction sequence [4].

35                   Reference [4]: Barold, S.S., "Cardiac Pacing  
Hemodynamics: The Pacemaker Syndrome," Cardio, 1991;  
08: (Sept) 36-51.

40                   Heldman, D. et al., "True Incidence of Pacemaker  
Syndrome," Pace, 1990; 13: 1742-1750.

45                   Aussbel, U., Furman, S., "The Pacemaker Syndrome, Ann  
(?) Internal Medicine," 1985; 103: 420-429.

Mode Selection Conclusion 49

50                   1.    Does the patient need a pacemaker?  
Yes.

2. Will the patient's need for a pacemaker  
be infrequent?

5

No.

4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

10

No.

5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

15

None.

11. What is the status of the sinus rhythm  
(Neuroregulatory abnormality, Normal, Sinus Node  
dysfunction)?

20

Sinus Node dysfunction.

12. Is AV Block present or is the patient on  
medications likely to cause AV Block?

30

No.

10. Does Atrial rate increase with  
physiologic stress?

35

No.

8. Is there a hypertrophied, non-compliant  
ventricle?

40

No.

9. Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
cardiac output) with ventricular pacing or pre-pacing  
native rhythm when AV synchrony is lost?

50

No.

55

14. Is AV node function normal even at higher rates?

Yes.

Recommended mode: AAIR

Mode Selection Conclusion 50

1. Does the patient need a pacemaker?

Yes.

2. Will the patient's need for a pacemaker be infrequent?

No.

4. Is the patient mentally incompetent, unaware of surroundings, in need of continual nursing care, etc?

No.

5. Is there evidence of Atrial fibrillation (None, Chronic, Intermittent)?

None.

11. What is the status of the sinus rhythm (Neuroregulatory abnormality, Normal, Sinus Node dysfunction)?

Sinus Node dysfunction.

12. Is AV Block present or is the patient on medications likely to cause AV Block?

No.

10. Does Atrial rate increase with physiologic stress?

No.

5 8. Is there a hypertrophied, non-compliant  
ventricle?

No.

10 9. Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
cardiac output) with ventricular pacing or pre-pacing  
native rhythm when AV synchrony is lost?

15 No.

20 14. Is AV node function normal even at higher  
rates?

No.

25 Recommended mode: DDIR

Mode Selection Conclusion 51

30 1. Does the patient need a pacemaker?  
Yes.

35 2. Will the patient's need for a pacemaker  
be infrequent?

No.

40 4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

45 No.

50 5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

55 None.

11. What is the status of the sinus rhythm  
(Neuroregulatory abnormality, Normal, Sinus Node  
dysfunction)?

Sinus Node dysfunction.

12. Is AV Block present or is the patient on  
medications likely to cause AV Block?

No.

10. Does Atrial rate increase with  
physiologic stress?

Yes.

8. Is there a hypertrophied, non-compliant  
ventricle?

Yes.

14. Is AV node function normal even at higher  
rates?

Yes.

Recommended Mode: AAI

Comment: Given the hypertrophied, non-compliant  
ventricle, one wants to maintain AV synchrony as much as  
possible when the atrium is NOT fibrillation. Hence VVI  
and VVIR are not appropriate in this setting.

Mode Selection Conclusion 52

1. Does the patient need a pacemaker?  
Yes.

2. Will the patient's need for a pacemaker  
be infrequent?

No.

5                   4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

10                               No.

                  5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

15                               None.

                  11. What is the status of the sinus rhythm  
(Neuroregulatory abnormality, Normal, Sinus Node  
dysfunction)?

Sinus Node dysfunction.

25                   12. Is AV Block present or is the patient on  
medications likely to cause AV Block?

                  No.

30                   10. Does Atrial rate increase with  
physiologic stress?

35                               Yes.

                  8. Is there a hypertrophied, non-compliant  
ventricle?

40                               Yes.

                  14. Is AV node function normal even at higher  
rates?

45                               No.

50                   Recommended Mode:     DDD

                  Comment: Given the hypertrophied, non-compliant  
ventricle, one wants to maintain AV synchrony as much as

55

possible when the atrium is NOT fibrillation. Hence VVI  
and VVIR are not appropriate in this setting.

5

Mode Selection Conclusion 53

10

1. Does the patient need a pacemaker?  
Yes.

15

2. Will the patient's need for a pacemaker  
be infrequent?  
No.

20

4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?  
No.

25

5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?  
None.

30

11. What is the status of the sinus rhythm  
(Neuroregulatory abnormality, Normal, Sinus Node  
dysfunction)?  
Sinus Node dysfunction.

35

40

12. Is AV Block present or is the patient on  
medications likely to cause AV Block?  
No.

45

10. Does Atrial rate increase with  
physiologic stress?  
Yes.

50

8. Is there a hypertrophied, non-compliant  
ventricle?

55

No.

5                   9.    Is there evidence of pacemaker syndrome  
                 (fall in blood pressure, retrograde conduction, fall in  
                 cardiac output) with ventricular pacing or pre-pacing  
10                  native rhythm when AV synchrony is lost?

Yes.

15                  14.   Is AV node function normal even at higher  
                 rates?

Yes.

20                  Recommended mode:   AAI Patient Disc:

                  Comment:   With documented pacemaker syndrome -  
                  whether it being during ventricular pacing or its  
25                  functional equivalent (a junctive rhythm with loss of AV  
                  synchrony, PVC: with retrograde conduction) it is  
                  essential to maintain an appropriate atrio-ventricular  
30                  contraction sequence [4].

                  Reference [4]: Barold, S.S., "Cardiac Pacing  
                  Hemodynamics: The Pacemaker Syndrome," Cardio, 1991; 8:  
35                  (Sept) 36-51.

                  Heldman, D. et al., "True Incidence of Pacemaker  
40                  Syndrome," Pace, 1990; 13: 1742-1750.

                  Aussbel, U., Furman, S., "The Pacemaker Syndrome, Ann  
45                  (?) Internal Medicine," 1985; 103: 420-429.

Mode Selection Conclusion 54

50                  1.    Does the patient need a pacemaker?  
                  Yes.

55

2. Will the patient's need for a pacemaker be infrequent?

5

No.

4. Is the patient mentally incompetent, unaware of surroundings, in need of continual nursing care, etc?

10

No.

5. Is there evidence of Atrial fibrillation (None, Chronic, Intermittent)?

15

None.

11. What is the status of the sinus rhythm (Neuroregulatory abnormality, Normal, Sinus Node dysfunction)?

20

Sinus Node dysfunction.

12. Is AV Block present or is the patient on medications likely to cause AV Block?

30

No.

10. Does Atrial rate increase with physiologic stress?

35

Yes.

8. Is there a hypertrophied, non-compliant ventricle?

40

No.

9. Is there evidence of pacemaker syndrome (fall in blood pressure, retrograde conduction, fall in cardiac output) with ventricular pacing or pre-pacing native rhythm when AV synchrony is lost?

50

Yes.

55

14. Is AV node function normal even at higher rates?

No.

Recommended Mode: DDD

Comment: With documented pacemaker syndrome - whether it being during ventricular pacing or its functional equivalent (a junctive rhythm with loss of AV synchrony, PVC: with retrograde conduction) it is essential to maintain an appropriate atrio-ventricular contraction sequence [4].

Reference [4]: Barold, S.S., "Cardiac Pacing Hemodynamics: The Pacemaker Syndrome," Cardio, 1991; 8: (Sept) 36-51.

Heldman, D. et al., "True Incidence of Pacemaker Syndrome," Pace, 1990; 13: 1742-1750.

Aussbel, U., Furman, S., "The Pacemaker Syndrome, Ann (?) Internal Medicine," 1985; 103: 420-429.

Mode Selection Conclusion 55

1. Does the patient need a pacemaker?  
Yes.

2. Will the patient's need for a pacemaker be infrequent?

No.

4. Is the patient mentally incompetent, unaware of surroundings, in need of continual nursing care, etc?

No.

5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

None.

11. What is the status of the sinus rhythm  
(Neuroregulatory abnormality, Normal, Sinus Node  
dysfunction)?

Sinus Node dysfunction

12. Is AV Block present or is the patient on  
medications likely to cause AV Block?

No.

10. Does Atrial rate increase with  
physiologic stress?

Yes.

8. Is there a hypertrophied, non-compliant  
ventricle?

No.

9. Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
cardiac output) with ventricular pacing or pre-pacing  
native rhythm when AV synchrony is lost?

No.

14. Is AV node function normal even at higher  
rates?

Yes.

Recommended Mode: AAI

Mode Selection Conclusion 56

1. Does the patient need a pacemaker?  
Yes.

5

2. Will the patient's need for a pacemaker  
be infrequent?

No.

10

4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

15

No.

5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

20

None.

11. What is the status of the sinus rhythm  
(Neuroregulatory abnormality, Normal, Sinus Node  
dysfunction)?

25

Sinus Node dysfunction.

30

12. Is AV Block present or is the patient on  
medications likely to cause AV Block?

35

No.

10. Does Atrial rate increase with  
physiologic stress?

40

Yes.

8. Is there a hypertrophied, non-compliant  
ventricle?

45

No.

9. Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
cardiac output) with ventricular pacing or pre-pacing  
native rhythm when AV synchrony is lost?

50

55

No.

5 14. Is AV node function normal even at higher  
rates?

No.

10

Recommended Mode: DDD

15

20

25

30

35

40

45

50

55

Mode Selection Conclusion 57

- 5                   1.    Does the patient need a pacemaker?  
                    Yes.
- 10                   2.    Will the patient's need for a pacemaker  
                    be infrequent?  
                    No.
- 15                   4.    Is the patient mentally incompetent,  
                    unaware of surroundings, in need of continual nursing  
                    care, etc?  
20                   No.
5.    Is there evidence of Atrial fibrillation  
25                   (None, Chronic, Intermittent)?  
                    None.
11.   What is the status of the sinus rhythm  
30                   (Neuroregulatory abnormality, Normal, Sinus Node  
                    dysfunction)?  
                    Sinus Node dysfunction  
35
12.   Is AV Block present or is the patient on  
                    medications likely to cause AV Block?  
40                   Yes.
10.   Does Atrial rate increase with  
45                   physiologic stress?  
                    No.
8.    Is there a hypertrophied, non-compliant  
50                   ventricle?  
                    Yes.
- 55                   Recommended Mode:    DDDR

5           Comment: Given the hypertrophied, non-compliant  
          ventricle, one wants to maintain AV synchrony as much as  
          possible when the atrium is NOT fibrillation. Hence VVI  
          and VVIR are not appropriate in this setting.

10           Mode Selection Conclusion 58

15                   1. Does the patient need a pacemaker?  
                      Yes.

20                   2. Will the patient's need for a pacemaker  
                      be infrequent?  
                      No.

25                   4. Is the patient mentally incompetent,  
                      unaware of surroundings, in need of continual nursing  
                      care, etc?  
                      No.

30                   5. Is there evidence of Atrial fibrillation  
                      (None, Chronic, Intermittent)?  
35                        None.

40                   11. What is the status of the sinus rhythm  
                      (Neuroregulatory abnormality, Normal, Sinus Node  
                      dysfunction) ?  
                      Sinus Node dysfunction

45                   12. Is AV Block present or is the patient on  
                      medications likely to cause AV Block?  
50                        Yes.

55                   10. Does Atrial rate increase with  
                      physiologic stress?  
                      No.

8. Is there a hypertrophied, non-compliant  
ventricle?

No.

9. Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
cardiac output) with ventricular pacing or pre-pacing  
native rhythm when AV synchrony is lost?

Yes.

Recommended mode: DDDR

Comment: With documented pacemaker syndrome -  
whether it being during ventricular pacing or its  
functional equivalent (a junctive rhythm with loss of AV  
synchrony, PVC: with retrograde conduction) it is  
essential to maintain an appropriate atrio-ventricular  
contraction sequence [4].

Reference [4]: Barold, S.S., "Cardiac Pacing  
Hemodynamics: The Pacemaker Syndrome," Cardio, 1991; 8:  
(Sept) 36-51.

Heldman, D. et al., "True Incidence of Pacemaker  
Syndrome," Pace, 1990; 13: 1742-1750.

Aussel, U., Furman, S., "The Pacemaker Syndrome, Ann  
(?) Internal Medicine," 1985; 103: 420-429.

#### Mode Selection Conclusion 59

1. Does the patient need a pacemaker?  
Yes.

2. Will the patient's need for a pacemaker  
be infrequent?

No.

5                   4.    Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

10                               No.

                  5.    Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

15                               None.

                  11.   What is the status of the sinus rhythm  
(Neuroregulatory abnormality, Normal, Sinus Node  
dysfunction)?

20                               Sinus Node dysfunction

25                   12.   Is AV Block present or is the patient on  
medications likely to cause AV Block?

30                               Yes.

                  10.   Does Atrial rate increase with  
physiologic stress?

35                               No.

                  8.    Is there a hypertrophied, non-compliant  
ventricle?

40                               No.

                  9.    Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
cardiac output) with ventricular pacing or pre-pacing  
native rhythm when AV synchrony is lost?

50                               No.

Recommended Mode:   DDDR

55

Mode Selection Conclusion 60

5

1. Does the patient need a pacemaker?  
Yes.

10

2. Will the patient's need for a pacemaker  
be infrequent?

No.

15

4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

20

No.

25

5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?

None.

30

11. What is the status of the sinus rhythm  
(Neuroregulatory abnormality, Normal, Sinus Node  
dysfunction)?

35

Sinus Node dysfunction.

40

12. Is AV Block present or is the patient on  
medications likely to cause AV Block?

Yes.

45

10. Does Atrial rate increase with  
physiologic stress?

Yes.

50

8. Is there a hypertrophied, non-compliant  
ventricle?

Yes.

55

Recommended Mode: DDD

5           Comment Given the hypertrophied, non-compliant  
ventricle, one wants to maintain AV synchrony as much as  
possible when the atrium is NOT fibrillation. Hence VVI  
10 and VVIR are not appropriate in this setting.

Mode Selection Conclusion 61

15           1. Does the patient need a pacemaker?  
Yes.

20           2. Will the patient's need for a pacemaker  
be infrequent?  
No.

25           4. Is the patient mentally incompetent,  
unaware of surroundings, in need of continual nursing  
care, etc?

30           No.

35           5. Is there evidence of Atrial fibrillation  
(None, Chronic, Intermittent)?  
None.

40           11. What is the status of the sinus rhythm  
(Neuroregulatory abnormality, Normal, Sinus Node  
dysfunction)?

45           Sinus Node dysfunction.

12. Is AV Block present or is the patient on  
medications likely to cause AV Block?

50           Yes.

10. Does Atrial rate increase with  
55 physiologic stress?

Yes.

5                   8.    Is there a hypertrophied, non-compliant  
ventricle?

No.

10                   9.    Is there evidence of pacemaker syndrome  
(fall in blood pressure, retrograde conduction, fall in  
cardiac output) with ventricular pacing or pre-pacing  
15 native rhythm when AV synchrony is lost?

Yes.

20 Recommended Mode:    DDD

                  Comment: With documented pacemaker syndrome -  
25 whether it being during ventricular pacing or its  
functional equivalent (a junctive rhythm with loss of AV  
synchrony, PVC: with retrograde conduction) it is  
essential to maintain an appropriate atrio-ventricular  
30 contraction sequence [4].

                  Reference [4]: Barold, S.S., "Cardiac Pacing  
35 Hemodynamics: The Pacemaker Syndrome," Cardio, 1991; 8:  
(Sept) 36-51.

                  Heldman, D. et al., "True Incidence of Pacemaker  
40 Syndrome," Pace, 1990; 13: 1742-1750.

                  Aussbel, U., Furman, S., "The Pacemaker Syndrome, Ann  
45 (?) Internal Medicine," 1985; 103: 420-429.

Mode Selection Conclusion 62

50

                  1.    Does the patient need a pacemaker?  
Yes.

55

2. Will the patient's need for a pacemaker be infrequent?

5

No.

4. Is the patient mentally incompetent, unaware of surroundings, in need of continual nursing care, etc?

10

No.

5. Is there evidence of Atrial fibrillation (None, Chronic, Intermittent)?

15

None.

11. What is the status of the sinus rhythm (Neuroregulatory abnormality, Normal, Sinus Node dysfunction)?

20

25

Sinus Node dysfunction

12. Is AV Block present or is the patient on medications likely to cause AV Block?

30

Yes.

10. Does Atrial rate increase with physiologic stress?

35

Yes.

8. Is there a hypertrophied, non-compliant ventricle?

40

No.

9. Is there evidence of pacemaker syndrome (fall in blood pressure, retrograde conduction, fall in cardiac output) with ventricular pacing or pre-pacing native rhythm when AV synchrony is lost?

50

No.

55

Recommended Mode: DDD Alternate: DDDR

5           Comment: While base rate pacing is all that is  
required at the time of implantation, progression of  
sinus or AV nodal conduction disease due to intrinsic  
10       pathologic processes or medications may render the  
patient chronotropically incompetent in the future.  
Rate modulated capability will allow for management of  
all options.

15

# Claims

- 20   1. A decision support system for providing guidance in programming an implantable cardiac stimulating device, comprising:  
  
a storage unit containing one or more rule sets defining rules for deriving operating parameters for one or  
more types of implantable cardiac stimulating devices;  
25   a rule engine unit which selects, from said plurality of rule sets, a rule set corresponding to a type of implantable  
cardiac stimulating device being programmed, and which conducts an interactive session defined in accordance  
with said rules of said selected rule set through which programming information is acquired, the programming  
information being used by said rule engine unit to determine an appropriate operating condition for  
said implantable cardiac stimulating device; and  
30   input/output means for enabling said rule engine unit to acquire said programming information during said  
interactive session and for presenting said operating condition determined by said rule engine unit.
2. The decision support system of claim 1 further comprising a patient/device database unit for storing medical information  
pertaining to patients and to said plurality of types of implantable cardiac stimulating devices.
- 35   3. The decision support system of claim 2, wherein said rule engine accesses said patient/device database and uses  
said medical information to select said rule set corresponding to said type of implantable cardiac stimulating device  
being programmed.
- 40   4. The decision support system of claim 2, wherein said rule sets are stored in said patient/device database unit.
5. The decision support system of claim 1 further comprising means for providing citations to medical literature which  
support said operating condition determined by said rule engine.
- 45   6. The decision support system of claim 5, wherein said means for providing citations presents said citations via said  
input/output means.
7. The decision support system of claim 1, wherein said rule engine unit comprises a microprocessor.
- 50   8. The decision support system of claim 1, wherein said storage unit stores said rule sets as decision trees.
9. The decision support system of claim 1, wherein said storage unit stores said rule sets as deduction-oriented,  
antecedent-consequent rules.
- 55   10. The decision support system of claim 1, wherein said input/output means comprises a device selected from the  
group consisting of a keyboard, a touch-sensitive screen, a screen with a light pen, or combinations thereof, to  
enable said rule engine to acquire said programming information and/or a device selected from the group consisting  
of a display monitor, a printer, a touch-sensitive screen, or combinations thereof, to enable said rule engine to

present said operating condition.

11. A method of providing decision support in programming of an implantable cardiac stimulating device, comprising the steps of:

5

obtaining medical information pertaining to a patient, and to a type of implantable cardiac stimulating device being programmed;

selecting a rule set, corresponding to said type of implantable cardiac stimulating device being programmed, from a plurality of rule sets stored in a storage unit;

10

conducting an interactive session defined in accordance with rules of said selected rule set through which programming information is acquired; and

using said programming information to determine an appropriate operating condition for said implantable cardiac stimulating device being programmed.

15

12. The method of claim 11 further comprising the step of telemetrically programming said implantable cardiac stimulating device being programmed in accordance with said operating condition.

13. The method of claim 11 or 12 carried out using a decision support system as claimed in any of claims 1 to 10.

20

14. An implantable cardiac stimulating device programmer comprising a decision support system as claimed in any of claims 1 to 10 said programmer further comprising:

telemetry means for communicating said operating condition to said implantable cardiac stimulating device.

25

15. The programmer of claim 14, wherein the rule engine is at least partially microprocessor-based.

30

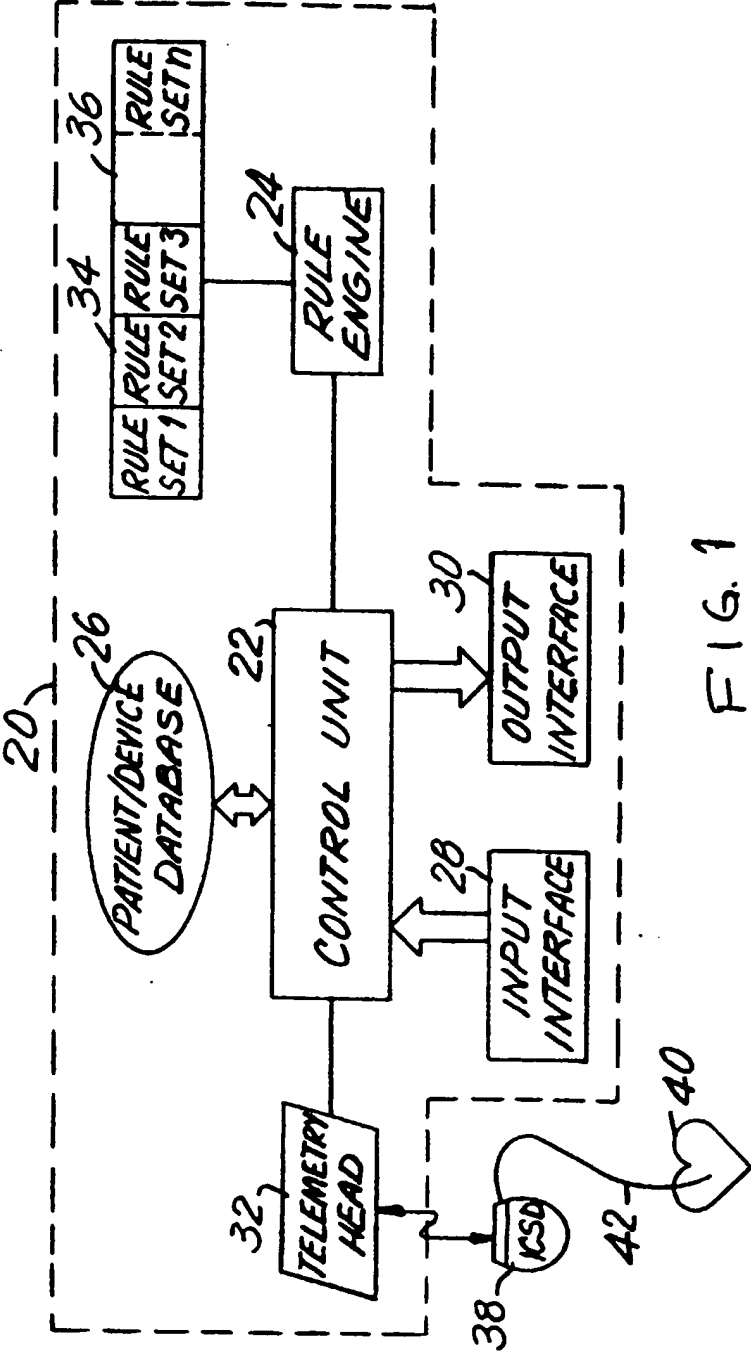
35

40

45

50

55



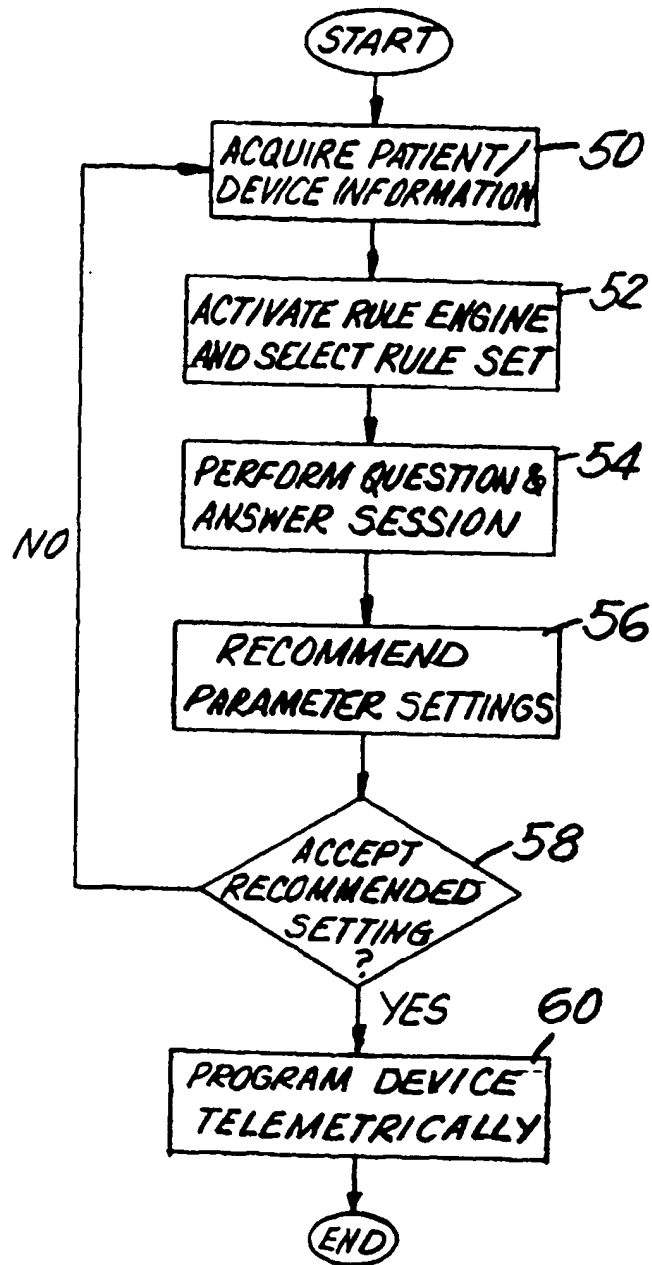
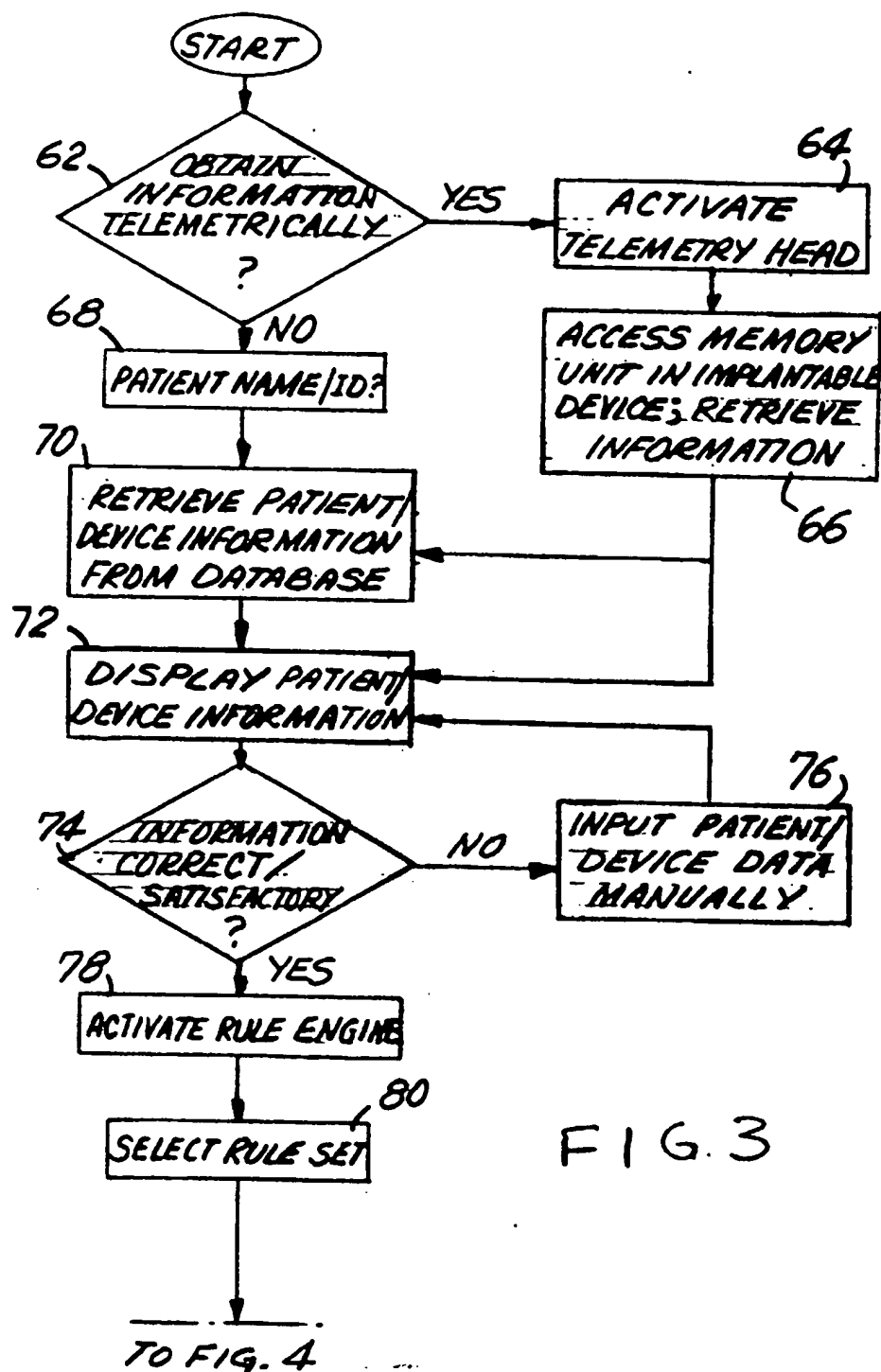
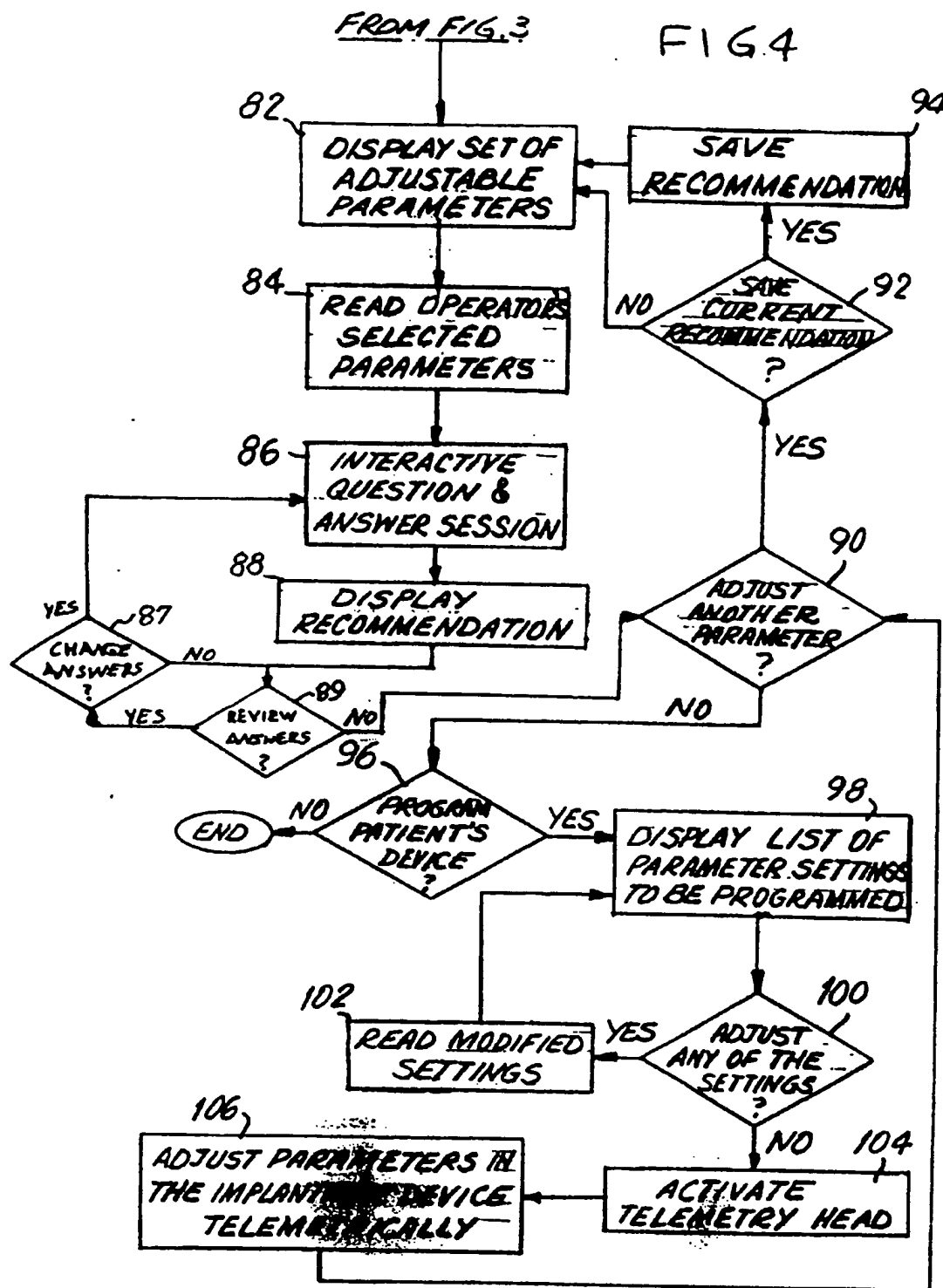


FIG. 2





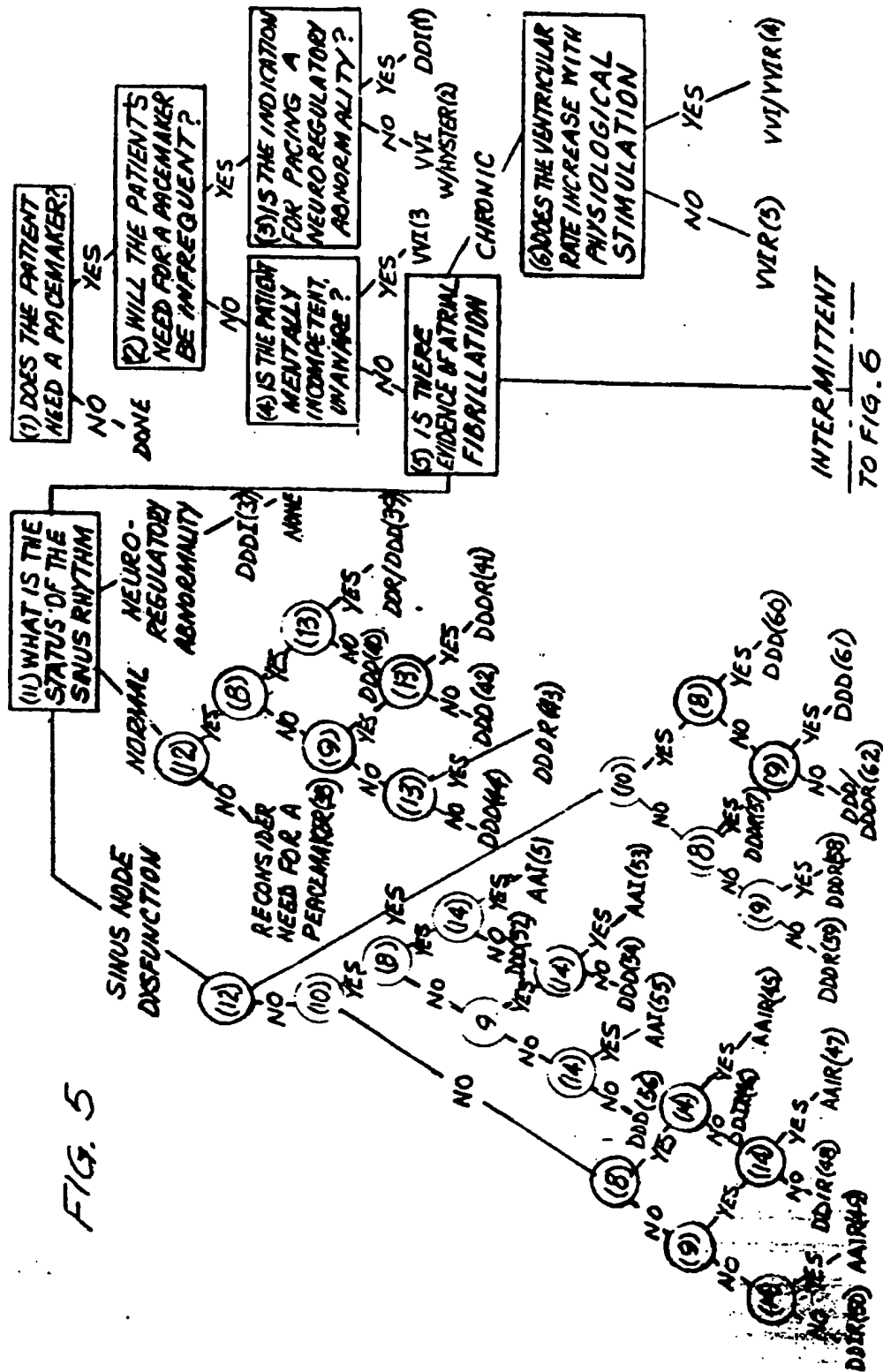


FIG. 6

FROM FIG 5

